COVIDIEN

Operator's Manual

Puritan Bennett™

980 Series Ventilator



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1 Introduction

1.1 Overview

This manual contains information for operating the Puritan Bennett™ 980 Series Ventilators. Before operating the ventilator system, thoroughly read this manual. The latest version of this manual is available on the Internet at:

http://www.covidien.com

To order an additional copy of this manual, contact Covidien Customer Service or your local representative.

1.1.1 Related Documents

Documentation is available online at the URL above. Covidien makes available all appropriate information relevant to use and service of the ventilator. For further assistance, contact your local Covidien representative.

- ***The*** Puritan Bennett™ 980 Series Ventilator ***Operator's Manual*** — Provides basic information on operating the ventilator and troubleshooting errors or malfunctions. Before using the ventilator, thoroughly read this manual.
- ***The*** Puritan Bennett™ 980 Series Ventilator ***Service Manual*** — Provides information to Covidien-trained service technicians for use when testing, troubleshooting, repairing, and upgrading the ventilator.

This chapter contains the following:

- Symbol definitions
- Safety Information, including Warnings, Cautions, and Notes
- Technical assistance information
- How to access on-screen Help
- How to access warranty information
- Serial number interpretation
- Information regarding Electromagnetic susceptibility

1.2 Global Symbol Definitions

The following table describes the symbols shown on the ventilator shipping cartons. Other symbols appearing on various labels are shown in *Chapter 2*.

Table 1-1. Shipping Carton Symbols and Descriptions

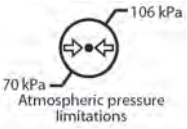
Symbol	Description
SN	Serial number
REF	Part number
	Manufacturer
	This side up
	Fragile
	Humidity limitations: 10% to 95% relative humidity, non-condensing (operation and storage)
	Temperature limitations: 10°C to 40°C (50°F to 104°F) (operation) -20°C to 70°C (-68°F to 158°F) (storage)
	Atmospheric pressure limitations: 70 kPa to 106 kPa (10.2 psi to 15.4 psi)
	Keep dry
	CSA certification mark that signifies the product has been evaluated to the applicable ANSI/Underwriters Laboratories Inc. (UL) and CSA standards for use in the US and Canada.

Table 1-1. Shipping Carton Symbols and Descriptions (Continued)

Symbol	Description
Rx ONLY	US federal law restricts this device to sale by or on the order of a physician.
	Refer to instruction manual.

1.3 Safety Information

1.3.1 Safety Symbol Definitions

This section contains safety information for users, who should always exercise appropriate caution while using the ventilator.

Table 1-2. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.

1.3.2 Warnings Regarding Fire Hazards



WARNING:
Explosion hazard — Do not use in the presence of flammable gases. An oxygen-rich environment accelerates combustibility.

WARNING:
To avoid a fire hazard, keep all components of the system away from all sources of ignition (such as matches, lighted cigarettes, flammable medical gases, and/or heaters). Oxygen-rich environments accelerate combustibility.

WARNING:
In case of fire or a burning smell, immediately take the following actions if it is safe to do so: disconnect the patient from the ventilator and disconnect the ventilator from the oxygen supply, facility power, and all batteries. Provide alternate method of ventilatory support to the patient, if required.

WARNING:
Replacement of batteries by inadequately trained personnel could result in an unacceptable risk, such as excessive temperatures, fire, or explosion.

WARNING:
To minimize fire hazard, inspect and clean or replace, as necessary, any damaged ventilator parts that come into contact with oxygen.

WARNING:
To prevent electrostatic discharge (ESD) and potential fire hazard, do not use antistatic or electrically conductive hoses or tubing in or near the ventilator breathing system.

1.3.3 General Warnings

WARNING:
To ensure proper operation and avoid the possibility of physical injury, only qualified medical personnel should attempt to set up the ventilator and administer treatment with the ventilator.

WARNING:
In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death. An alternative source of ventilation, such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4 with mask) should always be available when using the ventilator.

WARNING:
Patients on mechanical ventilation should be monitored by clinicians for proper patient ventilation.

WARNING:
The ventilator system is not intended to be a comprehensive monitoring device and does not activate alarms for all types of conditions. For a detailed understanding of ventilator operations, be sure to thoroughly read this manual before attempting to use the ventilator system.

WARNING:
To prevent patient injury, do not use the ventilator if it has a known malfunction. Never attempt to override serious malfunctions. Replace the ventilator and have the faulty unit repaired by trained service personnel.

WARNING:
To prevent patient injury, do not make unauthorized modifications to the ventilator.

WARNING:
To prevent injury and avoid interfering with ventilator operation, do not insert tools or any other objects into any of the ventilator's openings or ports.

WARNING:
The audio alarm volume level is adjustable. The operator should set the volume at a level that allows the operator to distinguish the audio alarm above background noise levels. Reference *To adjust alarm volume*, p. 3-41 for instructions on alarm volume adjustment.

WARNING:
Do not silence, disable, or decrease the volume of the ventilator's audible alarm if patient safety could be compromised.

WARNING:
If increased pressures are observed during ventilation, it may indicate a problem with the ventilator. Check for blocked airway, circuit occlusion, and/or run SST.

WARNING:
The LCD panel contains toxic chemicals. Do not touch broken LCD panels. Physical contact with a broken LCD panel can result in transmission or ingestion of toxic substances.

WARNING:
If the Graphical User Interface (GUI) display/LCD panel is blank or experiences interference and cannot be read, check the patient, then verify via the status display that ventilation is continuing as set. Because breath delivery is controlled *independently* from the GUI, problems with the display will not, by themselves, affect ventilation. The ventilator, however, should be replaced as soon as possible and repaired by qualified service personnel.

WARNING:
The Puritan Bennett™ 980 Series Ventilator contains phthalates. When used as indicated, very limited exposure to trace amounts of phthalates may occur. There is no clear clinical evidence that this degree of exposure increases clinical risk. However, in order to minimize risk of phthalate exposure in children and nursing or pregnant women, this product should only be used as directed.

WARNING:
Even though the 980 Series Ventilator meets the standards listed in *Chapter 11*, the internal Lithium-ion battery of the device is considered to be Dangerous Goods (DG) Class 9 - Miscellaneous, when transported in commerce. The 980 Series Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements may apply.

1.3.4 Warnings Regarding Environment of Use

WARNING:
Do not position the ventilator next to anything that blocks or restricts the gas inlet or cooling air circulation openings, gas exhaust port, fan intake, or alarm speaker, as this may:

- **limit the air circulation around the ventilator, potentially causing over-heating;**
- **limit the ventilator's ability to exhaust patient exhaled gas leading to potential harm;**
- **limit the clinician's ability to hear ventilator alarms.**

WARNING:
To avoid injury, do not position the ventilator in a way that makes it difficult to disconnect the patient.

WARNING:
To ensure proper operation, do not position the ventilator in a way that makes it difficult to access the AC power cord.

WARNING:
Do not use the ventilator in a hyperbaric chamber. It has not been validated for use in this environment.

WARNING:
Do not use the ventilator in the presence of strong magnetic fields. Doing so could cause a ventilator malfunction.

WARNING:
Do not use the ventilator during radiotherapy (i.e. cancer treatment using ionizing radiation), as doing so could cause a ventilator malfunction.

WARNING:
To avoid the risk of ventilator malfunction, operate the ventilator in an environment that meets specifications. Reference *Environmental Specifications*, p. 11-7.

WARNING:
Do not use the ventilator as an EMS transport ventilator. It has not been approved or validated for this use.

1.3.5 Warnings Before Using Equipment

WARNING:
Before activating any part of the ventilator, be sure to check the equipment for proper operation and, if appropriate, run SST as described in this manual. Reference *To run SST*, p. 3-48.

WARNING:
Check for leaks in the ventilator breathing system by running SST prior to ventilating a patient.

WARNING:
Lock the ventilator's casters during use to avoid the possibility of extubation due to inadvertent ventilator movement.

WARNING:
The ventilator accuracies listed in the Ventilator Settings, Alarm Settings, and Patient Data tables in *Chapter 11* are applicable only under specified operating conditions. Reference *Environmental Specifications*, p. 11-7. If the ventilator is operated outside specified ranges, the ventilator may supply incorrect information and the accuracies listed in the aforementioned tables do not apply. A hospital Biomedical Technician must verify the ventilator is operated in the environmental conditions specified.

1.3.6 Warnings Regarding Electrical Power

WARNING:
To avoid the risk of electrical shock:

- **Use only Covidien-branded batteries, adapters, and cables.**
- **Do not use batteries, adapters or cables with visible signs of damage.**
- **Do not touch internal components.**

1.3.7 Warnings Regarding Ventilator Settings

WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient, based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

WARNING:
Avoid nuisance alarms by applying appropriate alarm settings.

WARNING:
To prevent inappropriate ventilation, select the correct Tube Type (ET or Tracheostomy) and tube inner diameter (ID) for the patient’s ventilatory needs. Inappropriate ventilatory support leading to over-or under-ventilation could result if an ET tube or trach tube setting larger or smaller than the actual value is entered.

WARNING:
Setting expiratory volume alarms to OFF increases the risk of not detecting a low returned volume.

WARNING:
Setting any alarm limits to OFF or extreme high or low values can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention.

1.3.8 Warnings Regarding Hoses, Tubing, and Accessories

WARNING:
To prevent electrostatic discharge (ESD) and potential fire hazard, do not use antistatic or electrically conductive hoses or tubing in or near the ventilator breathing system.

WARNING:
Adding accessories to the ventilator can change the pressure gradient across the *ventilator breathing system (VBS)* and affect ventilator performance. Ensure that any changes to the ventilator circuit configurations do not exceed the specified values for circuit compliance and for inspiratory or expiratory limb total resistance. Reference *Technical Specifications*, p. 11-3. If adding accessories to the patient circuit, always run SST to establish circuit compliance and resistance prior to ventilating the patient.

WARNING:
Use of a nebulizer or humidifier can lead to an increase in the resistance of inspiratory and expiratory filters. Monitor the filters frequently for increased resistance or blockage.

WARNING:
During transport, the use of breathing tubing without the appropriate cuffed connectors may result in the circuit becoming detached from the ventilator.

WARNING:
The added gas from an external pneumatic nebulizer can adversely affect spirometry, delivered O_2%, delivered tidal volumes, and breath triggering. Additionally, aerosolized particulates in the ventilator circuit can lead to an increase in expiratory filter resistance.

WARNING:
Carefully route patient tubing and cabling to reduce the possibility of patient entanglement or strangulation.

WARNING:
Always use filters designed for use with the Puritan Bennett™ 980 Series Ventilator. Do not use filters designed for use with other ventilators. Reference *Covidien Accessories and Options*, p. 9-4 for relevant filter part numbers.

WARNING:
To avoid liquid entering the ventilator, empty the expiratory condensate vial before fluid reaches the maximum fill line.

WARNING:
Accessory equipment connected to the analog and digital interfaces must be certified according to IEC 60601-1. Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part of the ventilator system configures a medical system, and is therefore responsible for ensuring the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult Covidien Technical Services at 1.800.255.6774 or your local representative.

1.3.9 Warnings Regarding Gas Sources

WARNING:
Do not use nitric oxide, helium or mixtures containing helium with the ventilator. It has not been validated for use with these gas mixtures.

WARNING:
To avoid the risk of ventilator malfunction, do not use the ventilator with anesthetic gases.

WARNING:
For proper ventilator operation, use only clean, dry, medical grade gases when ventilating a patient.

WARNING:
Use of only one gas source could lead to loss of ventilation and/or hypoxemia if that one gas source fails and is not available. Therefore, always connect at least two gas sources to the ventilator to ensure a constant gas supply is available to the patient in case one of the gas sources fails. The ventilator has two connections for gas sources: air inlet, and oxygen inlet.

WARNING:
Use of the ventilator in altitudes higher or barometric pressures lower than those specified could compromise ventilator operation. Reference *Environmental Specifications*, p. 11-7 for a complete list of environmental specifications.

WARNING:
The ventilator should be connected to a gas pipeline system compliant to ISO 7396-1:2007 because:

- **Installation of the ventilator on a non-ISO 7396-1:2007 compliant gas pipeline system may exceed the pipeline design flow capacity.**
- **The ventilator is a high-flow device and can interfere with the operation of other equipment using the same gas source if the gas pipeline system is not compliant to ISO 7396-1:2007.**

1.3.10 Warnings Regarding Infection Control

WARNING:
Patients receiving mechanical ventilation may experience increased vulnerability to the risk of infection. Dirty or contaminated equipment is a potential source of infection. It is recognized that cleaning, sterilization, sanitation, and disinfection practices vary widely among health care institutions. Always follow your hospital infection control guidelines for handling infectious material. Follow the instructions in this manual and your institution's protocol for cleaning and sterilizing the ventilator and its components. Use all cleaning solutions and products with caution. Follow manufacturer's instructions for individual cleaning solutions. Reference *Chapter 7* of this manual.

WARNING:
To prevent infection and contamination, always ensure inspiratory and expiratory bacteria filters are installed before ventilating the patient.

WARNING:
Never attempt to re-use single patient use components or accessories. Doing so increases risk of cross-contamination and re-processing of single patient use components or accessories may compromise functionality leading to possible loss of ventilation.

1.3.11 Warnings Regarding Ventilator Maintenance

WARNING:
To ensure proper operation and avoid the possibility of physical injury, this ventilator should only be serviced by qualified technicians who have received appropriate Covidien-provided training for the maintenance of this ventilator.

WARNING:
Follow preventive maintenance according to specified intervals listed in these tables. Reference *Operator Preventive Maintenance Frequency*, p. 7-2. Reference *Service Preventive Maintenance Frequency*, p. 1-2 in the Operator's Manual Addendum on Preventive Maintenance.

1.3.12 Cautions

Caution:
To prevent possible equipment damage, ensure the casters are locked to prevent inadvertent movement of the ventilator during routine maintenance, or when the ventilator is on an incline.

Caution:
Do not use sharp objects to make selections on the display or keyboard.

Caution:
To ensure optimal performance, keep the GUI touch screen and keyboard clean and free from foreign substances. Reference *Surface Cleaning Agents*, p. 7-5.

Caution:
To avoid moisture entering the ventilator and possibly causing a malfunction, Covidien recommends using a wall air water trap when using piped medical air from a facility-based air compressor.

Caution:
Use only the cleaning agents specified. Reference *Surface Cleaning Agents*, p. 7-5. for approved cleaning agents.

Caution:
Do not block cooling vents.

Caution:
Ensure proper connection and engagement of expiratory and inspiratory filters.

Caution:
Follow instructions for proper GUI and BDU (breath delivery unit) mounting as described in the Puritan Bennett™ 980 Series Ventilator *Installation Instructions*.

Caution:
Follow proper battery installation instructions as described in this manual.

Caution:
When transferring the ventilator from storage conditions, allow its temperature to stabilize at ambient conditions prior to use.

Caution:
Remove extended and primary batteries from ventilator prior to transporting in a vehicle. Failure to do so could result in damage to the ventilator.

1.3.13 Notes

Note:
Federal law (USA) restricts the sale of this device except by or on the order of a physician.

Note:
When using non-invasive ventilation (NIV), the patient's actual exhaled volume may differ from the exhaled volume reported by the ventilator due to leaks around the mask.

Note:
When utilizing a closed-suction catheter system, the suctioning procedure can be executed using existing mode, breath type, and settings. To reduce potential for hypoxemia during the procedure, elevated delivered oxygen can be enabled using the Elevate O_2 control. Reference *To adjust the amount of elevated O_2 delivered for two minutes*, p. 3-40.

1.4 Obtaining Technical Assistance

1.4.1 Technical Services

For technical information and assistance, to order parts, or to order an Operator's Manual or Service Manual, contact Covidien Technical Services at 1.800.255.6774 or a local Covidien representative.Reference the following table for service centers in the USA and other countries. The Puritan Bennett™ 980 Series Ventilator *Service Manual* includes information necessary to service or repair the ventilator when used by qualified, factory-trained personnel.

When calling Covidien Technical Services, or a local Covidien representative, have the BDU and GUI serial numbers available, as well as the firmware version number of the ventilator system.

The ventilator's configuration is available by touching the wrench icon on the GUI screen, then touching the Options tab. Have this information available whenever requesting technical assistance.

Information on obtaining the Operator's and Service Manuals are available on the Internet at:

http://www.covidien.com

The following table lists Covidien Service Centers, addresses, telephone, and Fax numbers:

Covidien Argentina Aguero 351 Capital Federal - 1171 ABC, Argentina Tel: (5411) 4863-5300 Fax: (5411) 4863-4142	**Covidien Asia** Singapore Regional Service Centre 15 Pioneer Hub, #06-04 Singapore 627753 Tel (65) 6578 5288 Fax (65) 6515 5260	**Covidien Australia** 52A Huntingwood Drive Huntingwood, NSW 2148 Australia Tel: (+61) 1800 - 350702 Fax: (+61) 2967 - 18118	**Covidien Austria GmbH** Campus 21 Europaring F09402 A-2345 Brunn am Gebirge Tel: +43 (0) 2236 37 88 39 Fax: +43 (0) 2236 37 883940
Covidien Belgium BVBA/SPRL. Generaal De Wittelaan 9/5 2800 Mechelen Belgium Tel +32 15 29 44 50 Fax +32 15 29 44 55	**Covidien Brazil** Av. Das Nações Undias 12995 Andar 23 - Brooklin São Paulo, SP Brasil 04578-000 Tel: (5511) 2187-6200 Fax: (5511) 2187-6380	**Covidien Canada** 19600 Clark Graham Baie d'Urfe, QC, H9X 3R8 Canada Tel:1-514-332-1220, Select Option 2 Fax: 1-514-695-4965	**Covidien Chile** Camino lo Boza (Ex 8395) Pudehuel Santiago Chile Tel: (562) 739 - 3000 Fax: (562) 783 - 3149
Covidien China 2F, Tyco Plaza 99 Tian Zhou Rd Shang Hai 200233 P.R. China Tel: (+86) 4008 1886 86 Fax: (+86) 2154 4511 18	**Covidien Colombia** Edificio Prados de la Morea Carretera Central Del Norte (Cra 7a)Kilometro 18, Chia-Cundinamarca Bogota, Colombia Tel: (571) 619-5469 Fax: (571) 619-5425	**Covidien Costa Rica** Global Park, Parkway 50 La Auroa de Heredia Costa Rica Tel: (506) 2239 - 5386 Fax: (506) 2239 - 5319	**Covidien ECE** Prosecká 851/ 64 190 00 Prague Czech Republc Tel +42 024 109 57 35 Fax + 42 02 3900 0437
Covidien Danmark A/S Langebrogade 6E, 4. th DK-1411 København K Danmark Tel +45 4368 2171 Fax:+45 4368 2172	**Covidien Deutschland GmbH** Gewerbepark 1r D-93333 Neustadt/ Donau Germany Tel + 49 (0) 9445 95 9 0 Fax + 49 (0) 9445 95 9 155	**Covidien ECE** Galvahiho 7 / A 82104 Bratislava Slovakia Tel +420 2 41 095 735 Fax +420 2 39 000 437	**Covidien Finland Oy** Pursimiehenkatu 26-39C, PL407 FIN-00151 Helsinki Finland Te. +358 9725 192 88 Fax +358 9725 192 89
Covidien France SAS 2 Rue Denis Diderot 78990 Elancourt France Tel +33 (0) 13079 80 00 Fax +33 (0) 130 79 80 30	**Covidien Hong Kong** Unit 12 - 16, 18/F BEA Tower Millennium City 5 4187 Kwun Tong Road Kwum Tong, Kowloon, Hong Kong Tel + 852 3157 7299 Fax + 852 2838 0749	**Covidien India** 10th Floor Building No 9B DLF Cyber City Phase III Gurgaon Haryana - 122002 India Tel + 91 1244 709800 Fax + 91 1244 206850	**Covidien ECE** Mariássy u.7. 1095 Budapest Hungary Tel + 36 1880 7975 Fax + 36 1777 4932

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Covidien Korea 5F, Hibrand Living Gwan, #215, Yangjae-Dong, Seocho-Gu Seoul, Korea Tel: +822 570 5459 Fax: +822 570 5499	**Covidien Mexico** Insurgentes Sur # 863, Piso 16 Col. Nápoles Del. Benito Juarez Mexico, D.F. 03810 Mexico Tel: (5255) 5804-1524 Fax: (5255) 5536-1326	**Covidien Nederland BV** Hogeweg 105 NL5301 LL ZaltbommelNederland Tel0418 57 66 00 Fax 0418 57 67 91	**Covidien New Zealand** Cnr Manu Tapu Dr & Joseph Hammond Pl. Auckland Airport New Zealand Phone: + 64 508 489 264
Covidien Norge AS Bankveinen 1, Postboks 343 N-1372 Askerr Norway Tel +47 2415 98 87 Fax +47 2415 15 98 88	**Covidien Panama** Parque Industrial Costa del Esta Calle Primera, Edifio # 109 Panama City, Panama Tel: (507) 264-7337 Fax: (507) 236-7408	**Covidien Polska** Al. Jerozolimskie 162 02-342 Warszawa. Polska Tel +48 22 312 20 00 Fax +48 22 312 20 20	**Covidien Portugal Lda.** Produtos De Saúde Ida. Est: Outeiro Polima, Lote 10-1° Piso Abóboda P-2785-521 S. Domingos de Rana Portugal Tel +351 21 448 10 00 Fax +351 21 445 05 88
Covidien Puerto Rico Palmas Industrial Park Road 869 Km 2.0 Bdlg. #1 Cataño, PR 00962 Tel. 787-993-7250 Ext. 7222 & 7221 Fax 787-993-7234	**Covidien Russia** 53 bld. 5 Dubininskaya StreetMoscow RUSSIA. 119054 Tel +70 495 933 64 69 Fax +70 495 933 64 68	**Covidien Saglik A.S.** Maslak Mahallesi Bilim Sokak No: 5, Sun Plaza Kat: 2-3 Sisli, Istanbul 34398 Turkey Tel +90 212 366 20 00 Fax +90 212 276 35 25	**Covidien South Africa** Corporate Park North 379 Roan Crescent RandjesparkMidrand, South Africa Tel +27 115 429 500 Fax +27 115 429 624

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Covidien UK 4500 Parkway Whiteley, Fareham Hampshire PO157NY, United Kingdom Tel +44 (0) 1329 2240002 Fax +44 (0) 1329 220213	**Covidien USA** 2101 Faraday Ave Carlsbad, CA 92008 Phone: 1-800-255-6774 (option 4 Email: VentTechSup-port@covidien.com		

For online Technical support, visit the SolvIT℠ Center Knowledge Base at www.covidien.com. The SolvIT Center provides answers to frequently asked questions about the ventilator system and other Puritan Bennett products 24 hours a day, seven days a week.

1.4.2 On-Screen Help

The ventilator is equipped with an on-screen help system that enables users to select an item on the screen and display a description of that item. Follow the procedure below to access and use on-screen help.

Accessing On-screen Help Topics

Help topics on the ventilator are called tooltips. If a tooltip is available, a glowing blue outline appears around the item in question.

To access tooltips

1. Touch the item in question for a period of at least 0.5 s, or drag the help icon (the question mark icon appearing at the lower right of the GUI screen) to the item in question. A tooltip appears with a short description of the item. Most screen items have tooltips associated with them, providing the operator with access to a multitude of help topics.
2. Touch "more" on the dialog to display an expanded description.

3. Touch "close" to close the dialog, or let it fade away after five (5) seconds.

Note:

- Dragging the help icon causes the tooltip to display in its unexpanded state.
- Dragging the help icon and pausing causes a tooltip to display. Continue dragging to another item to dismiss the last tooltip and display another tooltip.

Other Resources

Additional resources for information about the ventilator can be found in the Puritan Bennett™ 980 Series Ventilator *Service Manual* and appendices in this manual for BiLevel 2.0, IE Sync, Leak Sync, PAV+, NeoMode 2.0, and Proximal Flow Sensor options.

1.5 Warranty Information

To obtain warranty information for a covered product, contact Covidien Technical Services at 1.800.255.6774 or call a local Covidien representative.

1.6 Manufacture Date

The graphical User Interface (GUI) and Breath Delivery Unit (BDU) each possess a specific year of manufacture applicable only for that assembly. These dates are contained in the serial numbers for each assembly or option. Serial numbers for the 980 Ventilator final units consist of ten digits, in the following format:

35ZYYXXXXX

where

- 35 signifies the unit was manufactured in Galway, Ireland
- Z represents the product code (B= breath delivery unit, G= GUI, P = Proximal Flow Monitoring option). The product codes shown here are typically the most common. There may be other product codes shown in the serial number depending upon the particular option(s) purchased.
- YY is a two-digit year code that changes with each year
- XXXXX is a sequential number that resets at the beginning of each new year

Serial numbers are located on labels on the back panels of the GUI and BDU, and in various locations on product options.

1.7 Manufacturer



Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

1.8 Electromagnetic Compatibility

The ventilator system complies with the requirements of IEC 60601-1-2:2007 (EMC Collateral Standard) including the E-field susceptibility requirements at a level of 10 volts per meter, at frequencies from 80 MHz to 2.5 GHz. However, even at this level of device immunity, certain transmitting devices (cellular phones, walkie-talkies, cordless phones, paging transmitters, RFID devices, etc.) emit radio frequencies that could interrupt ventilator operation if operated in a range too close to the ventilator. Practitioners should be aware of possible radio frequency interference if portable devices are operated in close proximity to the ventilator.

The Puritan Bennett™ 980 ventilator requires special precautions to be taken regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in *Chapter 11* in this manual.

2 Product Overview

2.1 Overview

This chapter contains introductory information for the Puritan Bennett™ 980 Series Ventilator.

Note:
Items shown in ***bold-italic*** font are contained as entries in the glossary.

Communication between the ventilator's ***graphical user interface (GUI)*** and the ***breath delivery unit (BDU)*** occurs continuously via independent ***central processing units (CPUs)***.

Reference *Pneumatic Diagram*, p. 2-37 and its associated reference designators when reading the following paragraphs.

Gas delivery starts with the ventilator connected to wall (or bottled) air and oxygen. Gas travels to the mix module where gas pressures are regulated by their respective ***proportional solenoid valves (PSOLs)***. The PSOLs meter the gases according to the ventilator settings entered, then the gases flow through individual air and oxygen flow sensors into the mix manifold and accumulator for mixing. The individual gas pressures are continuously monitored both before and after they are mixed in the mix manifold and accumulator assemblies. The mixed gas then flows to the inspiratory pneumatic system where it flows through the breath delivery flow sensor and then the inspiratory PSOL for delivery to the patient.

Before the gas reaches the patient, it passes through an internal inspiratory bacteria filter, then through an external inspiratory bacteria filter attached to the ventilator's gas outlet (the **To patient** port) where the breathing circuit is attached. When the gas returns from the patient, it flows through the expiratory limb of the breathing circuit, to the **From patient** port on the expiratory bacteria filter (which includes a condensate vial) before flowing through the exhalation valve flow sensor and ***exhalation valve (EV)***. A gas exhaust port allows exhaled gas to exit the ventilator and flow to the room.

The ventilator recognizes the patient's breathing effort using pressure triggering ***(P_{-TRIG})***, flow triggering ***($\dot{V}_{-TRIG}$)*** or IE Sync triggering (if the IE Sync Option is installed).*Reference Appendix C* for more information on the IE Sync Option. During pressure triggering, as the patient inhales, the airway pressure decreases and the inspiratory pressure transducer ***(PI)*** monitors this pressure decrease.When the pressure drops to at least the value of the pressure sensitivity ***(P_{SENS})*** setting, the ventilator delivers a breath. During flow triggering, the difference between inspiratory and expiratory flows is monitored. As the patient inhales, the exhalation valve flow sensor measures less flow, while the delivery flow sensor measurement remains constant. When the difference between the two measurements is at least the value of the operator-set flow sensitivity ***($\dot{V}_{SENS}$)***, the ventilator delivers a breath. If the patient is not inhaling, any difference between delivered flow and expiratory flow is due to flow sensor inaccuracy or leaks in the ventilator breathing circuit. To compensate for leaks, which can cause autotriggering, the clinician can increase the $\dot{V}_{SENS}$ setting or enable Leak Sync, if available.

Note:
Leak Sync is a software option. Details on its operation are provided in the Leak Sync appendix in this manual. *Reference Appendix B*.

A backup pressure triggering threshold of 2 cmH_2O is also in effect. This provides enough pressure sensitivity to avoid autotriggering, but will still allow the ventilator to trigger with acceptable patient effort.

The exhalation valve controls Positive End Expiratory Pressure ***(PEEP)*** using feedback from the expiratory pressure transducer ***(PE)***. The valve controller also cycles the ventilator into the exhalation phase if the PE measurement equals or exceeds the operator-set high circuit pressure limit. The PE measurement also controls when the safety valve ***(SV)*** opens. If PE measures 110 cmH_2O or more in the ventilator breathing circuit, the safety valve opens, allowing the patient to breathe room air (if able to do so) through the valve.

2.2 Ventilator Description

The ventilator system is available in three models. All ventilators provide continuous ventilation to patients requiring respiratory support.

- **Puritan Bennett™ 980 Pediatric - Adult Ventilator —** The Pediatric - Adult model ventilates Pediatric or Adult patients with predicted body weights from 3.5 kg to 150 kg, and with tidal volumes from 25 mL to 2500 mL.

- **Puritan Bennett™ 980 Neonatal Ventilator —** The Neonatal model ventilates Neonatal patients with predicted body weights from 0.3 kg to 7.0 kg, and with tidal volumes for mandatory volume-controlled breaths from 2 mL to 320 mL.
- **Puritan Bennett™ 980 Universal Ventilator —** The Universal model ventilates Neonatal, Pediatric, and Adult patients with predicted body weights from 0.3 kg to 150 kg, and with tidal volumes for mandatory volume-controlled breaths from 2 mL to 2500 mL.

To ventilate Neonatal patients on the Pediatric - Adult or Universal models, the NeoMode 2.0 software option is required. For details regarding the NeoMode 2.0 software option, *Reference Appendix E* in this manual.

The estimated service life of the ventilator is approximately 10 years, provided the preventive maintenance schedule stated in the Puritan Bennett™ 980 Series Ventilator *Service Manual* is followed; however, service life of individual units may vary.

The ventilator's IEC 60601-1/EN 60601-1 classification is:

- Protection class I
- Type BF
- Mobile
- Internally powered
- IP 21 equipment
- Continuous operation
- Not suitable for use with flammable medical gases (not AP or APG)

Reference *BDU Rear Label or Panel Symbols and Descriptions*, p. 2-11 for a description of the meaning of the IP classification.

The ventilator system uses a ***graphical user interface (GUI***) and ***breath delivery unit (BDU)*** for entering patient settings and delivering breaths to the patient. The GUI contains electronics capable of transferring the clinician's input (by touching the screen) to the BDU where pneumatic and electronic systems, respectively, generate the breathing parameters.

2.3 Indications For Use

The Puritan Bennett™ 980 Ventilator System is designed for use on patient population sizes from Neonatal (NICU) through Adult who require respiratory support or mechanical ventilation and weigh a minimum of 0.3 kg (0.66 lb). It is suitable for service in hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilatory support, delivered invasively or noninvasively, to patients who require the following types of ventilator support:

- Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask or nasal prongs)
- Assist/ Control, SIMV or Spontaneous modes of ventilation

Note:
Intended typical usage may be defined to include the following for the ventilator system:

Hospital Use — Typically covers areas such as general care floors (GCFs), operating rooms, special procedure areas, intensive and critical care areas within the hospital and in hospital-type facilities. Hospital-type facilities include physician office-base facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Intra-hospital transport — Includes transport of a patient within the hospital or hospital-type facility. All external hospital transportation (i.e. ambulance or aircraft) is excluded.

Note:
Federal law (USA) restricts the sale of this device except by or on the order of a physician.

2.4 Contraindications

Do not operate the ventilator in a magnetic resonance imaging (MRI) environment.

2.5 Components List

Note:
No parts of the ventilator system contain latex.

Note:
The components in the gas pathway that can become contaminated with bodily fluids or expired gases during both normal and single fault conditions are:

- External inspiratory filter
- Internal inspiratory filter
- Expiratory filter and condensate vial
- Exhalation valve assembly

The typical ventilator system ships with the following packing list. Depending upon the ventilator system purchased, your list may vary.

Table 2-1. Typical Packing List

Quantity	Item
1	Graphical User Interface
1	Breath Delivery Unit
1	Inspiratory filter
1	Expiratory filter
1	Condensate vial
2	Gas hoses (air and oxygen)
1	Standard caster base
1	Power cord
1	Operator's Manual CD
1	*Puritan Bennett™ 980 Series Ventilator Installation Instructions*
1	Flex arm
1	Drain bag
1	Gold standard circuit (for running EST)

2.6 Product Views

2.6.1 GUI Front View

Figure 2-1. GUI Front View



1 Display brightness key
2 Display lock key
3 Alarm volume key
4 Manual Inspiration key
5 Rotary encoder (knob)
6 Inspiratory pause key
7 Expiratory pause key
8 Alarm reset key
9 Alarm silence key

2.6.2 GUI Rear View

Figure 2-2. GUI Rear View



Reference *Common Symbols Found on GUI or BDU Labels*, p. 2-13 for symbols found on the GUI or BDU. The "Do Not Push" symbol found on the GUI, only, is shown in this table.

2.6.3 BDU Front View

Figure 2-3. BDU Front View



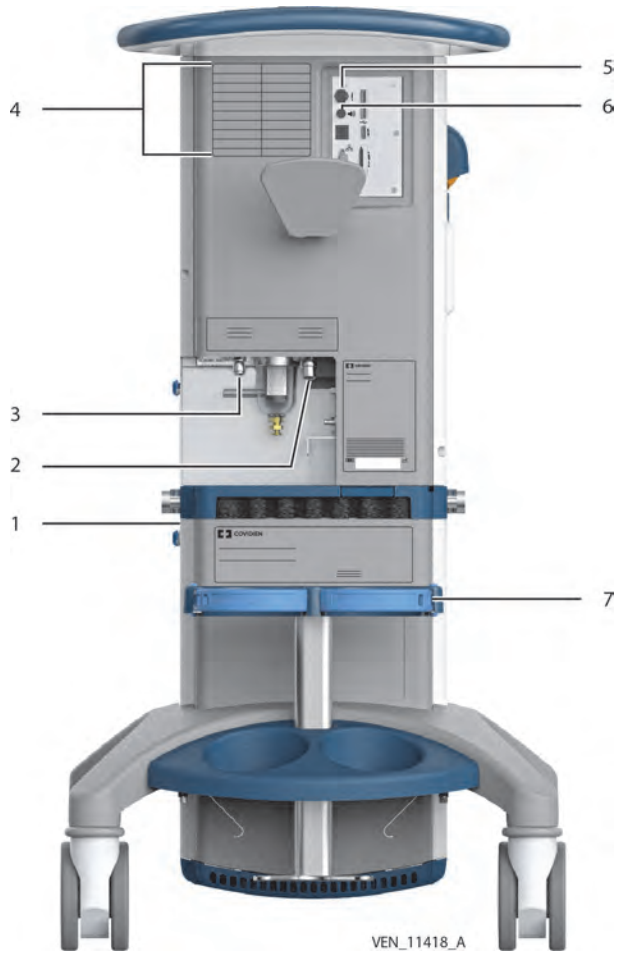
1	Condensate vial	5	Power switch
2	Expiratory filter	6	Status display
3	Expiratory filter latch	7	Internal inspiratory filter
4	AC power indicator	8	Option connector panel door

Table 2-2. BDU Front Label Symbols and Descriptions

Symbol	Description
	To Patient port
	From Patient port
	Expiratory filter latch locked (down)/unlocked (up)

2.6.4 BDU Rear View

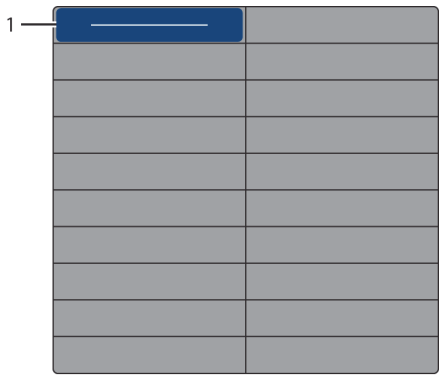
Figure 2-4. BDU Rear View



1	Standard base	5	Service mode button
2	Air inlet	6	Remote alarm port
3	Oxygen inlet	7	Cylinder mount (optional)
4	Labels indicating installed software options		

Software option labels are applied to the grid located on the back of the ventilator, as shown below and in the previous image (item 4).

Figure 2-5. Installed Software Options



The following table lists the symbols and descriptions found on BDU or base labels.

Table 2-3. BDU Rear Label or Panel Symbols and Descriptions

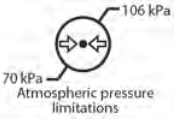
Symbol	Description
Rx ONLY	US federal law restricts this device to sale by or on the order of a physician.
	User must consult instructions for use. Symbol is also found on "Do not obstruct" labels on both left and right sides of the ventilator, and on label indication supply gas connections.
	Keep away from fire or flame. Oxygen rich environments accelerate combustibility.
	Atmospheric pressure limitations – The operational atmospheric pressure range 70 kPa to 106 kPa (10.2 psi to 15.4 psi).
	Humidity limitations – The operational humidity limit range 10% to 95%.
	Temperature limitations – The operational temperature limit range 50°F to 104°F (10°C to 40°C).

Table 2-3. BDU Rear Label or Panel Symbols and Descriptions (Continued)

Symbol	Description
	Type BF applied part.
IP21	IEC Ingress protection classification – Protected against ingress of fingers or similar objects and protected from condensation.
	Explosive hazard. Do not use in the presence of flammable gases.
	Authorized to bear the CSA certification mark signifying the product has been evaluated to the applicable ANSI/Underwriters Laboratories Inc. (UL) and CSA standards for use in the US and Canada.
	The ventilator contains components manufactured with phthalates.
	Unsafe to use the ventilator in magnetic resonance imaging environments.
	Potential equalization point (ground) (on AC panel).
CB1	BDU Circuit Breaker (on AC panel).
CB2	Compressor Circuit Breaker (on AC panel).
	USB port (at rear of ventilator).
HDMI	HDMI port (at rear of ventilator).
SERVICE	Service port (at rear of ventilator).

Table 2-3. BDU Rear Label or Panel Symbols and Descriptions (Continued)

Symbol	Description
TEST	Service mode button (at rear of ventilator).
	Remote alarm port (at rear of ventilator).
	Ethernet connector (at rear of ventilator).
	Serial port (at rear of ventilator).

Table 2-4. Common Symbols Found on GUI or BDU Labels

Symbol	Description
	Do Not Push - Do not push on the GUI
	Manufacturer - Name of the ventilator manufacturer.
SN	Serial number.
	Manufacture date – The manufacture date is contained in the serial number. Reference *Manufacture Date*, p. 1-19 for details regarding interpretation of the serial number.
	WEEE – Proper waste disposal. Follow local governing ordinances regarding disposing of waste labeled with the WEEE symbol.

2.6.5 Ventilator Side Views

Figure 2-6. Ventilator Right Side View

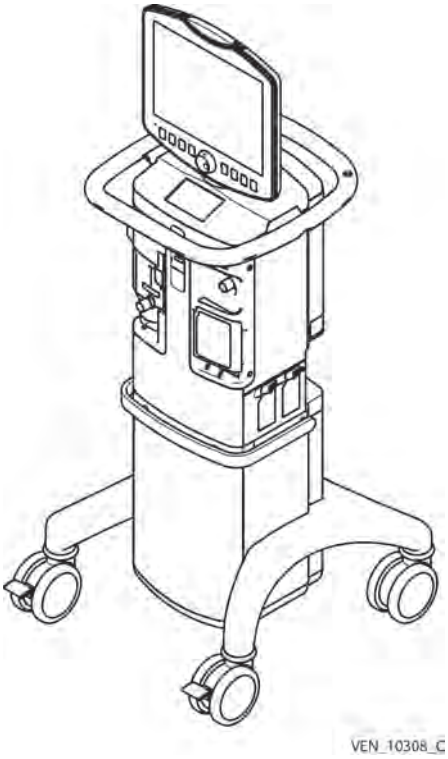
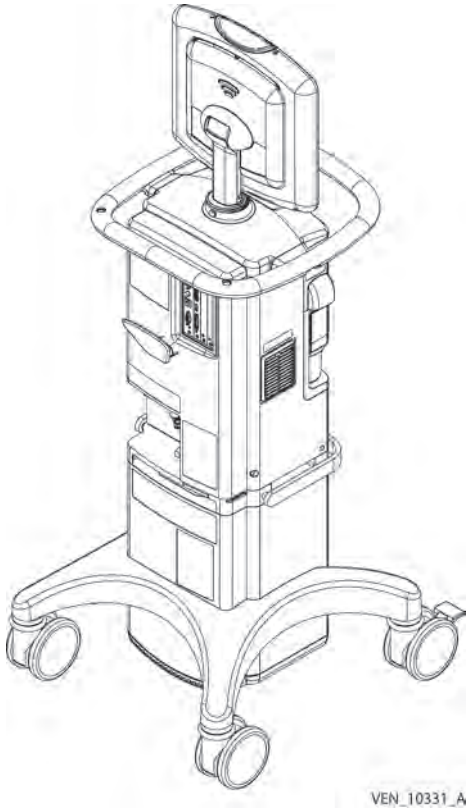


Figure 2-7. Ventilator Left Side View



2.7 Mounting Configurations

The ventilator system can be mounted as a free-standing unit standing at the patient's bedside; the BDU with the GUI is mounted on a base with casters and includes a handle for ease of movement.

2.8 Battery Backup

The ventilator system uses a battery to provide backup power in case AC power is lost. When operating on battery power, the status display shows the "On Battery Power" image, and the GUI displays a representation of battery charge levels. Reference *Typical Status Display Indicators and Messages*, p. 2-30 to for a description of the status display images and messages. An optional, extended battery is available to lengthen the amount of time the ventilator can operate on battery power. Reference *Using Battery Power*, p. 3-3.

2.9 Graphical User Interface

There are two displays on the ventilator — the primary display (GUI) and the status display.

2.9.1 Primary Display

The GUI incorporates a 15" display that rotates throughout a 170° angle about a vertical axis in either direction. The GUI can also be tilted up to 45° from vertical.

The clinician enters ventilation parameters via the GUI's touch screen, also known as the ventilator's primary display. The GUI's keys activate other ventilator functions including screen brightness, display lock, alarm volume, manual inspiration, inspiratory pause, expiratory pause, alarm reset, and alarm silence.

The GUI displays the following information depending on the state of the ventilator:

- Ventilator, apnea, and alarm settings
- Patient data
- Waveforms
- Current alarm banners

2.10 GUI Controls and Indicators

2.10.1 Control Keys

The GUI bezel has eight off-screen control keys as shown below.

Table 2-5. GUI Control Keys

Key symbol	Description
 	Brightness control key — Adjusts the GUI screen brightness. Press the key and turn the knob to adjust the brightness.

Table 2-5. GUI Control Keys (Continued)

Key symbol	Description
	Display lock key — Actuates a lock to prevent inadvertent settings changes to the ventilator (including the knob function) while the display is locked. The display lock is useful when cleaning the touch screen. Press the key again to unlock the display.
	Alarm volume key — Adjusts the alarm volume. The alarm volume cannot be turned OFF.
	Manual inspiration key — In A/C, SIMV, and SPONT modes, delivers one manual breath to the patient in accordance with the current mandatory breath parameters. In BiLevel mode, transitions from low pressure (P_L) to high pressure (P_H) (or vice versa). To avoid breath stacking, a manual inspiration is not delivered during inspiration or during the restricted phase of exhalation. Reference *Manual Inspiration*, p. 10-22 for information on the restricted phase of exhalation. The Manual inspiration key can be used to deliver mandatory breaths to the patient or to run an inspiratory pause maneuver in SPONT mode. The manual inspiration key cannot be used to run an expiratory pause maneuver in SPONT mode.
	Inspiratory pause key — Initiates an inspiratory pause which closes the inspiratory and exhalation valves and extends the inspiratory phase of a mandatory breath for the purposes of measuring end inspiratory pressure ($P_{I\ END}$) for calculation of plateau pressure (P_{PL}), static compliance (C_{STAT}), and static resistance (R_{STAT}).
	Expiratory pause key — Initiates an expiratory pause which extends the expiratory phase of the current breath in order to measure total PEEP ($PEEP_{TOT}$).
	Alarm reset key — Clears active alarms or resets high-priority alarms and cancels an active alarm silence. An alarm reset is recorded in the alarm log if there is an active alarm. DEVICE ALERT alarms cannot be reset.
	Alarm silence key — Silences alarms for two minutes. Cancel the alarm silence function by touching the on-screen "Cancel" button.

2.10.2 Visual Indicators

The table below shows the GUI's visual indicators. Reference *Areas of the GUI*, p. 4-3 for area names.

The alarm silence function has two visual indicators — the alarm silence key on the GUI bezel glows yellow during an alarm silence interval, and a visual count-

down timer appears, showing the amount of time the alarm silence interval has remaining.

Table 2-6. GUI Visual Indicators

Symbol	Description
	Ventilator Setup (Vent Setup) button. Located at the lower left corner of the GUI. Touch this button to open the ventilator setup screen.
	Adult patient circuit indicator. Indicates adult circuit type tested during SST, and in use. Appears above the Vent Setup button.
	Pediatric patient circuit indicator. Indicates pediatric circuit type tested during SST, and in use.Appears above the Vent Setup button.
	Neonatal patient circuit indicator. Indicates neonatal circuit type tested during SST, and in use.Appears above the Vent Setup button.
	Home icon. A constant access icon. Reference *Areas of the GUI*, p. 4-3. Touch this icon to dismiss all open dialogs on the GUI screen. The display resumes showing the ventilator waveforms.
	Alarms icon. A constant access icon. Reference *Areas of the GUI*, p. 4-3.Touch this icon to display the alarm settings screen, which allows alarm limits to be changed.
	Logs icon. A constant access icon. Reference *Areas of the GUI*, p. 4-3. Touch this icon to display the logs screen, which contains tabs for Alarms, Settings, Patient Data, Diagnostics, EST/SST status, General Event, and Service logs.

Table 2-6. GUI Visual Indicators (Continued)

Symbol	Description
	Elevate O_2 control. A constant access icon. Reference *Areas of the GUI*, p. 4-3. Touch this icon to increase the set the elevated oxygen concentration to the institutional default O_2 configuration (if institutional default has been configured) for two minutes, or allows the operator to determine the additional percentage of oxygen to increase. The O_2 concentration for the two-minute increase can be set to any value between 1% and 100% O_2. If the Elevate O_2 function is active, touching *Extend* re-starts the two-minute interval. The Elevate O_2 function can be terminated prior to completion of the two-minute interval by touching *Stop*. Any time the Elevate O_2 control is activated, an entry is made to the patient data log.
	Screen capture icon. A constant access icon. Reference *Areas of the GUI*, p. 4-3. Touch this icon to capture the image displayed on the GUI screen. Reference *To capture GUI screens*, p. 5-2 to read the complete procedure for capturing screen images.
	Help icon. A constant access icon. Reference *Areas of the GUI*, p. 4-3. Drag this icon to the item in question and release. A tooltip will appear describing the item's function.
	Unread items icon. When this icon appears overlaid on another icon or tab (the logs icon, for example) it indicates there are unread items at this location.
	Configure icon. A constant access icon. Reference *Areas of the GUI*, p. 4-3. Touch this icon to display the configure screen. Tabs with SST results, options, Comm setup, and date/ time change are displayed.
	Pause icon. Located above the constant access icons. Touch this icon to pause the waveform graph.
	Waveform layout icon. Located above the constant access icons area.Touch this icon to open the waveform layout dialog.

Table 2-6. GUI Visual Indicators (Continued)

Symbol	Description
	Grid lines icon. Located above the constant access icons area. Touch this icon to turn waveform grid lines ON or OFF.
	Maximize waveform icon. Located at the upper right portion of each waveform. Touch this icon to enlarge the waveform to its maximum size.
	Restore waveform icon. Restores waveform to its original size. Located at the upper right of the maximized waveform.
	Pushpin icon – pinned state. When in the pinned state, prevents a dialog from closing (under certain conditions). Located in the upper right corner of the GUI on the vent setup screen. Reference *Pushpin Icon*, p. 4-5.
	Pushpin icon – unpinned state. When the unpinned icon is touched, the pinned state becomes active. Located in the upper right corner of the GUI on the vent setup screen. Reference *Pushpin Icon*, p. 4-5.
!	Low priority alarm icon (appears on alarm banner).
!!	Medium priority alarm icon (appears on alarm banner).
!!!	High priority alarm icon (appears on alarm banner).

2.10.3 On-screen Symbols and Abbreviations

Touch an on-screen symbol briefly (0.5 *s*) to display a tooltip on the GUI screen. The tooltip contains a definition of the symbol and other descriptive text, available with either short or long descriptions. The short description expands to show more information by touching “more” on the tooltip dialog or collapses by touching “less”. The tooltip closes by touching “close” or fades in five (5) seconds if left alone. Expanding the tooltip dialog prevents the tooltip from timing out. Touching outside the tooltip causes the dialog to close.

The table below summarizes the ventilator’s symbols and abbreviations.

Table 2-7. Symbols and Abbreviations

Symbol or Abbreviation	Definition
T_A	Apnea interval
D_{SENS}	Disconnect sensitivity
C_{DYN}	Dynamic compliance
R_{DYN}	Dynamic resistance
EEF	End expiratory flow
$P_{I\ END}$	End inspiratory pressure
LEAK	Exhalation leak
$V_{TE\ MAND}$	Exhaled mandatory tidal volume
$\dot{V}_{E\ TOT}$	Exhaled minute volume
$\dot{V}_{E\ SPONT}$	Exhaled spontaneous minute volume
$V_{TE\ SPONT}$	Exhaled spontaneous tidal volume
V_{TE}	Exhaled tidal volume
E_{SENS}	Expiratory sensitivity
T_E	Expiratory time
	Flow pattern (ramp)
	Flow pattern (square)
$\dot{V}_{SENS}$	Flow sensitivity
$\dot{V}_{-TRIG}$	Flow triggering
P_H	High pressure setting (in BiLevel)
T_H	High pressure time (in BiLevel)
T_H:T_L	High pressure time to Low pressure time ratio (in BiLevel)
I:E	Inspiratory Time to Expiratory Time (I:E)
C_{20}/C	Inspiration compliance ratio
V_{LEAK}	Inspiratory leak
T_I	Inspiratory time

Table 2-7. Symbols and Abbreviations (Continued)

Symbol or Abbreviation	Definition
P_I	Inspiratory pressure
V_{TI}	Inspired tidal volume
V_{TL}	Inspired tidal volume (when Leak Sync is enabled)
$PEEP_I$	Intrinsic PEEP (auto PEEP)
$PEEP_{I\ PAV}$	PAV-based intrinsic PEEP
P_L	Low pressure setting (in BiLevel)
T_L	Low pressure time (in BiLevel)
P_{MEAN}	Mean circuit pressure
NIF	Negative inspiratory force
O_2%	Oxygen percentage
$P_{0.1}$	Airway occlusion pressure at 100 ms
C_{PAV}	PAV-based lung compliance
E_{PAV}	PAV-based lung elastance
% Supp	Percent support setting for Tube Compensation and PAV+
R_{PAV}	PAV-based patient resistance
R_{TOT}	PAV-based total airway resistance
WOB_{TOT}	PAV-based work of breathing of patient and ventilator during inspiration
P_{PEAK}	Peak circuit pressure
PEF	Peak expiratory flow
$\dot{V}_{MAX}$	Peak inspiratory flow
PSF	Peak spontaneous flow
PEEP	Set or monitored positive end expiratory pressure
%Leak	Percent leak
P_{PL}	Plateau pressure
T_{PL}	Plateau time
P_{COMP}	Compensation pressure

Table 2-7. Symbols and Abbreviations (Continued)

Symbol or Abbreviation	Definition
P_{SENS}	Pressure sensitivity
P_{SUPP}	Pressure support level
P_{-TRIG}	Pressure triggering
V_{TIY}	Proximal inspired tidal volume
V_{TEY}	Proximal exhaled tidal volume
$V_{TI\ MANDY}$	Proximal mandatory inspired tidal volume
$V_{TI\ SPONTY}$	Proximal spontaneous inspired tidal volume
V_{TLY}	Proximal inspired tidal volume with Leak Sync enabled
f	Respiratory rate or apnea respiratory rate
⌐P	Rise time percent
f/V_T	Spontaneous rapid/shallow breathing index
$T_{I\ SPONT}$	Spontaneous inspiratory time
T_I/T_{TOT}	Spontaneous inspiratory time ratio
C_{STAT}	Static compliance
R_{STAT}	Static Resistance
V_T	Tidal Volume
$PEEP_{TOT}$	Total PEEP
f_{TOT}	Total Respiratory Rate (monitored)
VC	Vital Capacity
VS	Volume support

2.10.4 Audible Indicators

A tone sounds when a button on the GUI is touched, and also when settings are accepted. Audible indicators include pitched tones, beeps, and key clicks. Key clicks sound whenever a key on the GUI is pressed. Various tones annunciate patient alarms.

Note:
Pressing ALARM SILENCE mutes alarms for the two-minute alarm silence duration period.

Caregivers may choose to silence alarms by pressing the ALARM SILENCE key. A two-minute countdown timer appears on the GUI during the alarm silence interval. Cancel the alarm silence function by touching *Cancel*.

Click each icon below to listen to a sample of the corresponding tones:

Note:
To hear the tones, Adobe Acrobat Reader version 10 or higher must be installed on your computer. *Get Adobe Acrobat Reader, free, here.*

Table 2-8. GUI Audible Indicator Functions

Function	Description
Low priority alarm tone	A series of two tones. Sounds when a low priority alarm occurs.
Medium priority alarm tone	A repeating series of three tones. Sounds when a medium priority alarm occurs.
High priority alarm tone	A repeating series of five tones. Sounds when a high priority alarm occurs.
Soft bound tone	One tone. Sounds when a soft bound is reached when making changes to ventilator settings. A soft bound is a selected value that exceeds or goes below its limit and requires acknowledgment to continue.
Hard bound tone (invalid entry)	The invalid entry sound occurs when a hard bound is reached when making changes to ventilator settings. A hard bound defines the upper or lower limit of the setting, where the setting cannot be adjusted higher or lower.

The clinician enters ventilation parameters via the GUI's touch screen. Reference *GUI Front View*, p. 2-6. The keys activate other ventilator functions. Reference *GUI Control Keys*, p. 2-16.

2.11 Breath Delivery Unit

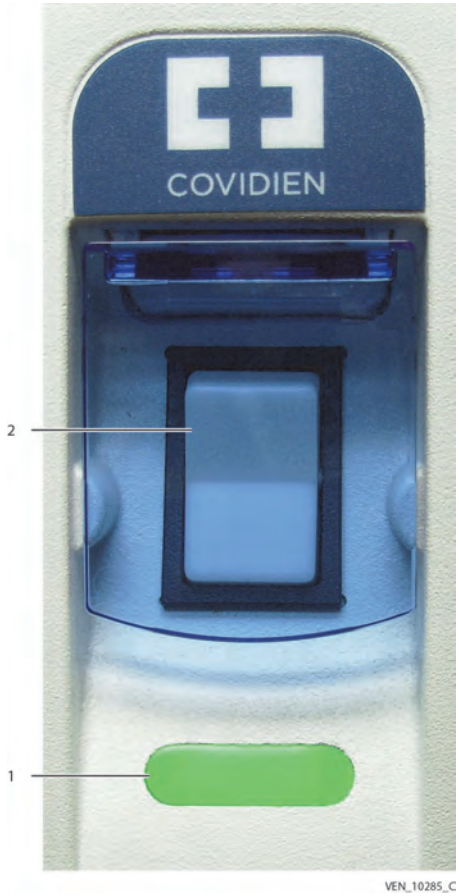
The breath delivery unit contains the hardware and software to enable the ventilator to provide patient support.

2.11.1 BDU Controls and Indicators

BDU Controls

- ON/OFF switch — Lift the switch cover and turn the ventilator ON or OFF.

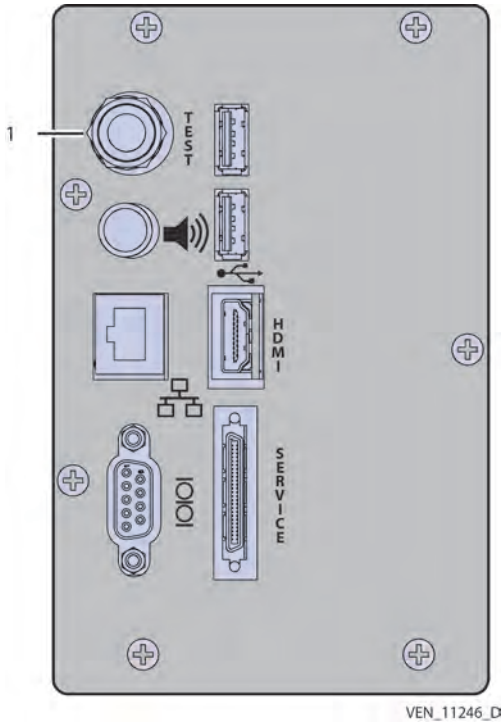
Figure 2-8. Ventilator Power Switch and AC Indicator



1	AC power indicator	2	ON/OFF switch

- Service mode button — Press and release this button when the Covidien splash screen appears on the status display after powering on the ventilator to enter Service mode. Reference *Service Mode Button (TEST)*, p. 2-27. Reference *Status Display Indicators and Descriptions*, p. 2-30 for an image of the splash screen.

Figure 2-9. Service Mode Button (TEST)



1 Service mode button

Note:
The Covidien splash screen shows the Covidien logo and appears momentarily as a banner on the status display.

BDU AC Indicator

The status display and the AC power indicator are the only visual indicators on the BDU. The AC indicator illuminates green whenever the ventilator is connected to AC power. All other visual indicators on the ventilator are on the GUI. Reference *Typical Status Display Indicators and Messages*, p. 2-30 for a description of the status display indicators and symbols. Reference the section below for a summary of the information appearing on the status display.

Status Display

The status display is a separate display located on the BDU. Reference *BDU Front View*, p. 2-8, item 6. The status display provides the following information according to the state of the ventilator:

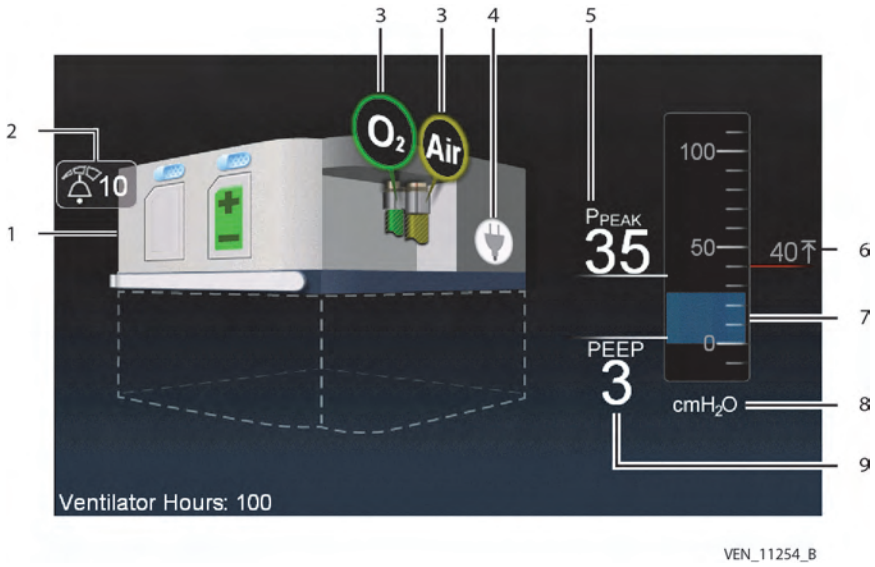
During normal ventilation the status display shows

- Current power source (AC or DC)
- Safe State status: (Safety Valve Open (SVO) or Vent Inop
- Presence of primary and extended batteries and their charging status
- Relative available battery charge level
- Circuit pressure graph displaying pressure units, $\uparrow P_{PEAK}$ alarm setting and current P_{PEAK} and PEEP values
- Connection of air and oxygen
- Ventilator operational hours
- Visual indication of current alarm volume setting

Note:
The status display provides a redundant check of ventilator operation.If the GUI stops operating for any reason, ventilation continues as set.

The figure below shows a sample of the status display during normal ventilation.

Figure 2-10. Sample Status Display During Normal Ventilation



1	Primary and extended battery status (presence or absence).	6	P_{PEAK} alarm setting
2	Alarm volume setting	7	Measured inspiratory pressure (changes as pressure changes)
3	Gas connection status	8	Selected pressure units
4	Power status	9	Measured PEEP
5	Measured peak circuit pressure (updated at the end of the current breath)		

During Service mode the status display supplies

- Ventilator serial number(s)
- Ventilator operational time
- EST and SST history
- Power On Self Test (POST) status
- Hours until next preventive maintenance is due
- Gas pressure at the manifold inlets

Reference the table below for status display possibilities.

Typical Status Display Indicators and Messages

The following table lists indicators and messages that appear on the status display:

Table 2-9. Status Display Indicators and Descriptions

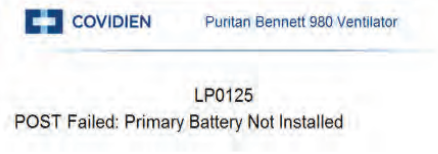
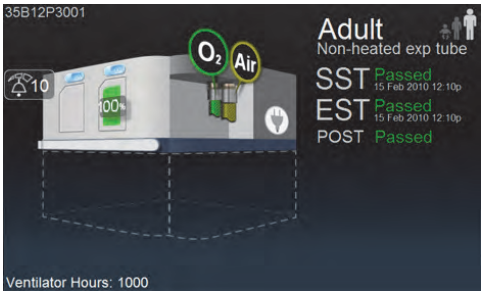
Status Display Indicator or Message	Meaning
	Splash screen. Appears when the ventilator's power switch is turned on. When this image appears, press and release the TEST button at the back of the ventilator to enter Service mode.
	POST failure. This image appears if a POST error occurs at ventilator start-up, along with the error code (in this case a missing primary battery).
	Prior to patient connection. The status display appears as shown when the patient has not been connected to the ventilator. Note the absence of P_{PEAK} and PEEP values.

Table 2-9. Status Display Indicators and Descriptions (Continued)

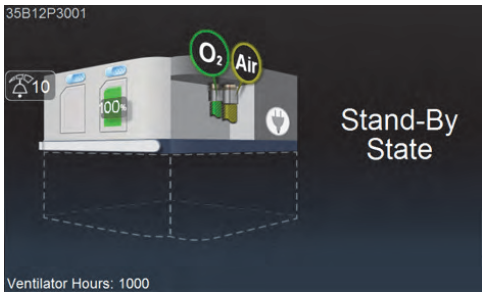
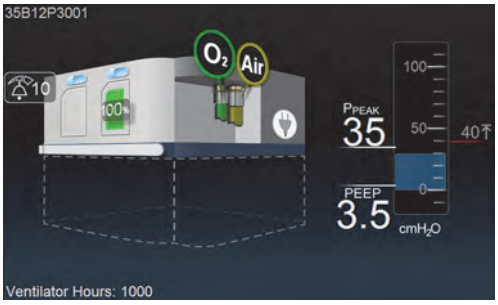
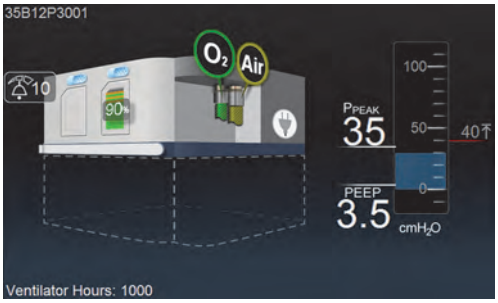
Status Display Indicator or Message	Meaning
	Stand-by state. The status display appears as shown when the ventilator is in stand-by state.
	Battery charged. The ventilator's primary battery (in the right-most slot) is shown fully charged. The percentage indicator shows 100%.
	Battery charging/discharging. Identifies that the ventilator's primary battery and/or extended battery is charging or discharging. This icon is animated; orange bars scroll upward indicating the battery is charging and downward when the battery is discharging. If the orange bars are absent, the battery is neither charging nor discharging. A percentage indicator shows the remaining battery capacity. If an extended battery is installed, the image shows a similar representation in the extended battery location (left-most slot).
	Battery icon. Denotes the ventilator is operating on battery power when this image appears on any status display indicator. Alerts the operator there is insufficient AC power to operate the ventilator. The indicator is replaced by the "on AC power" indicator when adequate AC power is restored.

Table 2-9. Status Display Indicators and Descriptions (Continued)

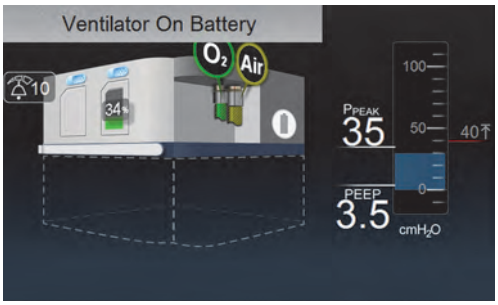
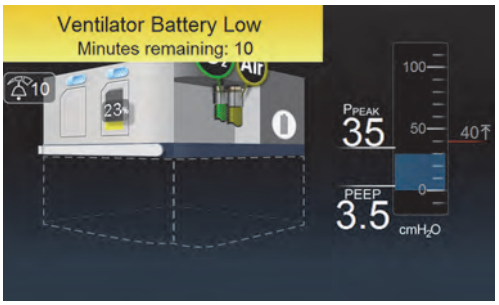
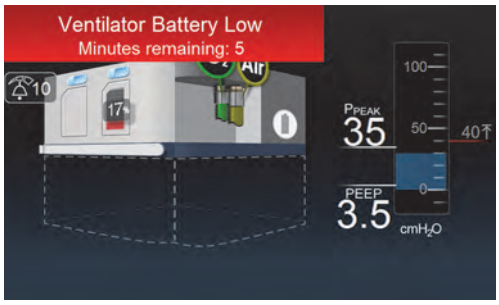
Status Display Indicator or Message	Meaning
	On battery power. Alerts the operator there is insufficient AC power to operate the ventilator. Ventilator is operating on battery power with greater than ten minutes of capacity remaining. Note the appearance of the battery icon.
	Low battery. Identifies that the ventilator's primary battery (right-most slot) is discharging and there are ten minutes or less of battery capacity remaining. A percentage indicator shows the remaining battery capacity. If an extended battery is installed, the image would show a similar representation in the extended battery location (left-most slot).
	Critically low battery. Identifies that the ventilator's primary battery has less than five minutes of battery capacity remaining. A percentage indicator shows the remaining battery capacity. If an extended battery is installed, the image would show a similar representation in the extended battery location.
	Power failure. Alerts the user that the ventilator's battery is depleted or depletion is imminent. Replace primary or extended battery with a fully charged batter or connect ventilator to AC power.

Table 2-9. Status Display Indicators and Descriptions (Continued)

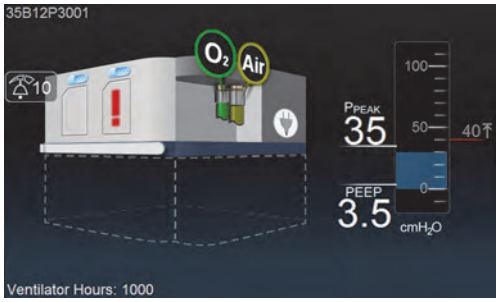
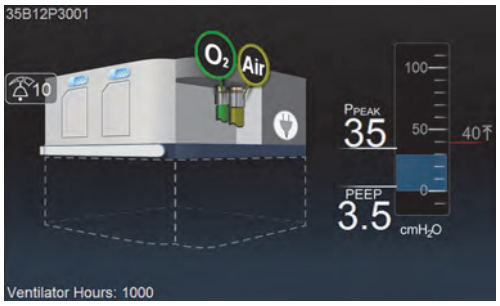
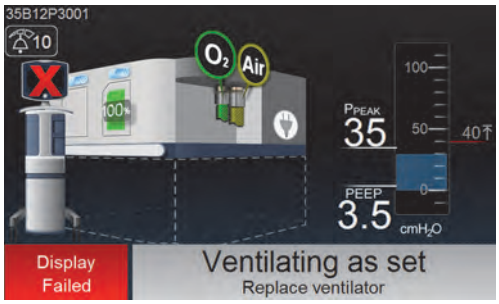
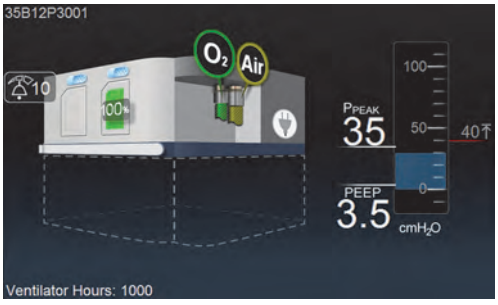
Status Display Indicator or Message	Meaning
	Battery inoperative. This image appears on the status display when a battery fault renders the battery inoperative.
	Battery not installed. This image appears when there is no primary battery installed, and renders ventilator inoperative. This image displays when the primary battery is removed during ventilator operation.
	Loss of GUI. Indicates a loss of communication between the BDU and the GUI, where the GUI cannot reliably display or receive ventilator information. This loss of communication could be caused by problems such as a GUI hardware failure, faulty Ethernet, or GUI reset. If the indicator is visible, ventilation continues as currently set. Replace the ventilator as soon as it is appropriate to do so. Service the ventilator prior to returning it for use on patients.
	Ventilator inoperative (Vent Inop). Indicates the ventilator is no longer capable of ventilating a patient and requires service. The alarm reset key cannot be used to restore function to the ventilator during a ventilator inoperative condition. Provide alternate means of ventilation immediately. Note the display of the Safety Valve Open indicator.

Table 2-9. Status Display Indicators and Descriptions (Continued)

Status Display Indicator or Message	Meaning
	Safety Valve Open (SVO) indicator. During SVO, the patient can breathe room air through the safety valve, to the extent the patient is able to breathe unaided. Reference *Safety Valve Open (SVO)*, p. 4-36 for more information on the SVO state.
	On AC power indicator. When this image appears on any status display indicator, indicates the ventilator is operating on AC power.
	Status display appearance when the ventilator is breathing in Normal mode. Note the appearance of the AC power icon.
	Air available indicator. When this image appears on any status display indicator, indicates the ventilator is connected to a pressurized air source.
	O_2 available indicator. When this image appears on any status display indicator, indicates the ventilator is connected to a pressurized O_2 source.

BDU Audible Indicators

The continuous tone alarm is the only audible indicator in the BDU, and is described in the table, below.

Table 2-10. BDU Audible Indicator Functions

Indicator	Description
Continuous tone alarm (Immediate priority)	A continuous tone annunciated when there is a Ventilator Inoperative (Vent Inop) condition. This alarm lasts for a minimum of two (2) minutes.

2.11.2 Connectors

The ventilator incorporates the following connectors:

- **Ventilator outlet port (To patient) —** A coaxial 15 mm (ID) / 22 mm (OD) conical connection to which the external inspiratory bacteria filter attaches.
- **Exhalation port (From patient) port —** The expiratory limb of the patient circuit attaches to the inlet of the expiratory bacteria filter. This port is compatible with a standard 22mm (OD) conical connection.
- **Proximal Flow sensor —** A keyed pneumatic connector for the Proximal Flow Sensor is provided with a locking feature to prevent inadvertent disconnection. The proximal flow sensor measures flow and pressure at the patient wye. The Proximal Flow Sensor is an optional sensor. Details on operation are provided in the appendix in this manual. *Reference Appendix F*.
- **Standard interface connectors —** USB, HDMI, and Ethernet connectors are provided. The USB connector allows images to be captured on an external USB storage device and allows communication with an external patient monitor via serial-over-USB protocol, and the HDMI connector allows the GUI image to be displayed on an external video display device. The Ethernet connector is used by Service Personnel to upload new software and options. Reference *Port Use*, p. 5-19 for more information. Reference *To configure Comm ports*, p. 5-4 for information on serial-over-USB data transfer when configuring Comm ports for external devices.

2.12 Special Features

A Proximal Flow option is available. The proximal Flow Sensor is used to measure low flows and pressures associated with neonatal ventilation. If the ventilator is configured with this option, *Reference Appendix F* for more information.

2.13 Color Definitions

Reference the following figures to view the ventilator's pneumatic diagram during inspiration with various colors representing the gases as shown below.

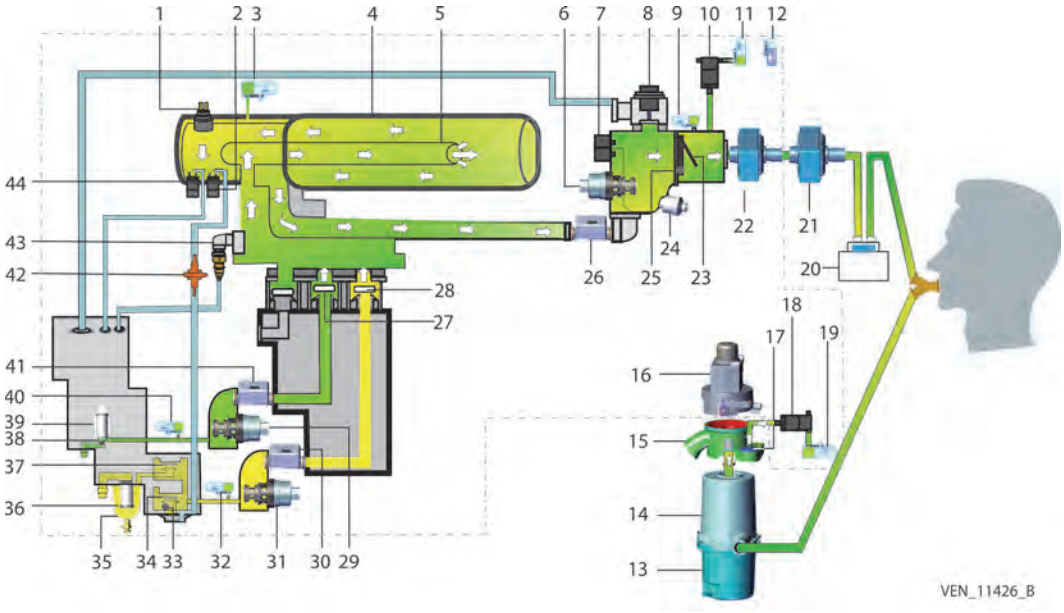
Table 2-11. Color Legend

Color or Symbol	Description
	High-pressure Oxygen (NFPA 99 designation)
	High-pressure Air (NFPA 99 designation)
	Mixed gases, including air
	Atmosphere
	Vacuum
	Water

2.14 Pneumatic Diagrams

The following figures illustrate the ventilator's pneumatics with and without the optional Proximal Flow System. The Proximal Flow System is only for use with neonatal patients.

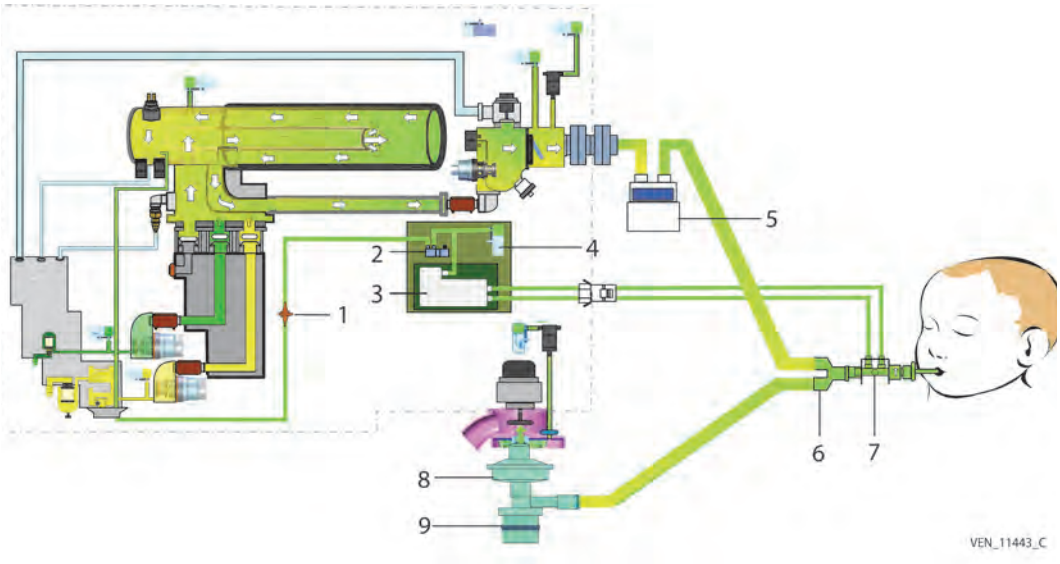
Figure 2-11. Pneumatic Diagram



1	Pressure switch, mix accumulator (PS1)	12	Pressure Sensor, barometric (P_A)
2	Solenoid Valve, options supply (SOL2)	13	Vial, exhalation condensate (ECV)
3	Pressure sensor, mix accumulator (P_{MX})	14	Filter, expiratory (F4)
4	Accumulator, mix (ACC_M)	15	Flow sensor assembly, exhalation valve
5	Tube, mix (T_M)	16	Exhalation valve (EV)
6	Proportional solenoid valve, patient gas delivery ($PSOL_D$)	17	Filter, exhalation pressure line (F5)
7	Solenoid valve, BUV (SOL3)	18	Solenoid valve, exhalation pressure autozero (SOL5)
8	Safety valve (SV)	19	Pressure sensor, exhalation (P_E)
9	Pressure Sensor, safety valve (P_{SV})	20	Humidifier
10	Solenoid valve, inspiratory pressure sensor autozero (SOL4)	21	Filter, External bacterial (F_{D2})
11	Pressure Sensor, inspiratory (P_I)	22	Filter, Internal bacterial (F_{D1})

23	Check valve, patient gas delivery (CV_D)	34	Check valve, compressor air inlet (CV_{CAir})
24	Sensor, oxygen (OS)	35	Filter bowl assembly, Air (WT2)
25	Restrictor, breath delivery bypass (R2)	36	Filter element, Air (F2)
26	Flow sensor, patient gas delivery (FS_D)	37	Check valve, wall Air inlet (CV_{WAir})
27	Check valve, Oxygen (CVO_2)	38	Filter, Oxygen Impact (F1)
28	Check valve, Air (CV_{Air})	39	Filter element, Oxygen (F3)
29	Proportional solenoid valve, Oxygen ($PSOLO_2$)	40	Pressure sensor, Oxygen gas inlet (PO_2)
30	Flow sensor, Air (FS_{Air})	41	Flow sensor, Oxygen (FSO_2)
31	Proportional solenoid valve, Air ($PSOL_{Air}$)	42	Restrictor, Prox Flow (R4)
32	Pressure sensor, air gas inlet (P_{Air})	43	Relief Valve, mix accumulator (RV_{MA})
33	Restrictor, Wall air bleed outlet (R1)	44	Solenoid Valve, mix accumulator purge (SOL1)

Figure 2-12. Pneumatic Diagram — Optional Proximal Flow System



Note:
Items enclosed by dotted line represent components internal to the ventilator.

1	Restrictor, Prox Flow (R4)	6	Wye, patient circuit
2	Solenoid Valve, Prox Flow (SOL 6)	7	Sensor, Proximal Flow
3	Module, Proximal Flow System	8	Filter, neonatal expiratory
4	Pressure Sensor, Prox Flow Accumulator (P_{PROX})	9	Condensate vial, neonatal expiratory
5	Humidifier		

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3 Installation

3.1 Overview

This chapter contains information for the installation and set up of the Puritan Bennett™ 980 Series Ventilator. Before operating the ventilator system, thoroughly read this Operator's Manual.

Topics include:

- Safety reminders
- Ventilator setup
- Battery information
- Ventilator operating modes
- Preparing the ventilator for use
- Tests to perform prior to ventilating a patient

3.2 Safety Reminders

WARNING:
Explosion hazard — Do not use in the presence of flammable gases. An oxygen-rich environment accelerates combustibility.

WARNING:
To ensure proper operation and avoid the possibility of physical injury, only qualified medical personnel should attempt to set up the ventilator and administer treatment with the ventilator.

WARNING:
To prevent electrostatic discharge (ESD) and potential fire hazard, do not use antistatic or electrically conductive hoses or tubing in or near the ventilator breathing system.

WARNING:
Use only gas supply hoses approved by Covidien. Other hoses may be restrictive and may cause improper ventilator operation.

WARNING:
To avoid possible injury, lock the ventilator's casters prior to installing or removing ventilator components.

Caution:
To ensure optimum performance, Covidien recommends preventive maintenance be performed by factory-trained Biomedical Engineers per the schedule specified. Reference *Service Preventive Maintenance Frequency*, p. 1-2 in the Operator's Manual Addendum in this manual.

Note:
US federal law restricts this device to sale by or on the order of a physician.

3.3 Product Assembly

3.3.1 How to Assemble Ventilator Components

Ventilator setup should have already been completed by factory-trained service personnel including successfully passing EST. This manual does not include ventilator assembly instructions.

3.3.2 Product Power Sources

Using AC Power

The ventilator is normally AC-powered. Reference *Connecting the Ventilator to AC Power*, p. 3-5 to connect the ventilator to AC power.

Using Battery Power

WARNING:
Use only Covidien-branded batteries. Using other manufacturer's brands could result in the batteries operating the ventilator for less than the specified amount of time or could cause a fire hazard.

WARNING:
One primary battery must be installed at all times in the BDU's primary battery slot for proper ventilator operation. The ventilator will not complete the startup process without the primary battery installed. Reference *Battery Compartment Locations*, p. 3-21 for identification of battery slots.

The ventilator's primary battery must be installed by qualified service personnel (as it is shipped separately) before patient use. The ventilator will not complete ***Power on Self Test (POST)*** if the battery is not present, and ventilation is prohibited. Ensure the battery is fully charged before placing the ventilator into service.

The ventilator employs a battery backup system if AC power becomes unavailable or drops below approximately 90 volts. A new, fully charged battery provides at least one hour of power to the ventilator assuming ambient temperature of 20°C (68°F) to 25°C (77°F), PBW = 70 kg, and at factory default ventilator settings.

The battery back-up system for the ventilator contains one primary battery. Backup power is supplied to the ventilator in the event of an AC power loss.

One extended battery slot is available for the ventilator. If both primary and extended ventilator batteries are present, these batteries can power the ventilator for two hours (one hour for the primary battery and one hour for the extended battery) under the environmental conditions described above. When using battery power, the ventilator operates from its extended batteries, if present, first and then switches to the primary batteries. The ventilator primary and extended batteries are charged whenever the ventilator is plugged into AC power (the ventilator does not have to be powered up). If the ventilator is operating on battery power, the status display shows which battery is in use and its charge level, and the remaining time the battery will operate before charging is required again.

Battery Charging

Batteries requiring charging are charged whenever the ventilator is connected to AC power, whether operating or not.

The ventilator charges its primary battery first, then its extended battery. The time required to charge a single battery (either primary or extended) is approximately six hours at room temperature whether the ventilator is turned off (but connected to AC power) or operating, but charging time can vary based on temperature or depletion state of the battery. The status display provides the battery's capacity.

Green LED bars located on the ends of both primary and extended batteries (if installed) scroll upwards indicating battery charging. A white LED bar represents the battery is in use and a round LED indicator illuminates red if there is a battery fault. When running on battery power, battery capacity is determined by the number of green LED bars illuminated. Reference *Proper Battery Orientation*, p. 3-20 to view the LEDs. Reference *p. 3-19* for information on interpreting the battery capacity. Green LED bars do not scroll if the battery is not charging or is in use.

If a battery fault occurs, the fault is annunciated, charging of the faulty battery discontinues, but charging of any other non-faulty battery continues. A faulty battery will cause annunciation of the error and battery power will not be available for the ventilator.

The ventilator status display indicates the charge level of the installed batteries, the presence of one or more battery faults, and which battery is being charged.

The ventilator operates no differently when its batteries are charging than it does when the batteries are fully charged.

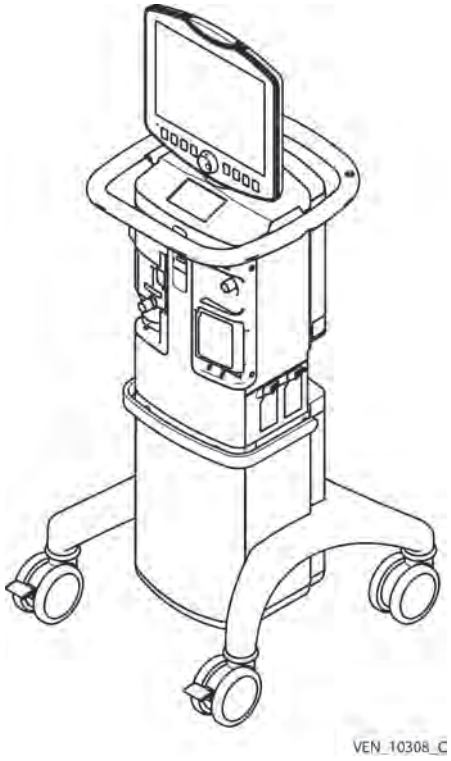
The ventilator continues operating as set when the ventilator switches from AC power to battery power and illuminates an indicator on the status display alerting the operator that the ventilator is now operating on battery power and AC POWER LOSS alarm annunciates. A medium priority alarm annunciates when the remaining run-time for the ventilator drops to ten (10) minutes and a high priority alarm annunciates when the remaining time drops to five (5) minutes.

3.4 Product Placement

The ventilator is positioned standing on its casters next to the patient's bedside, as shown below.

Move the ventilator using the handle encircling the BDU and roll the ventilator to the desired location.

Figure 3-1. Example of Freestanding Ventilator Placement



3.5 Product Connectivity

3.5.1 Connecting the Ventilator to AC Power

Note:
Power outlet access and power cord position — Ensure that the power outlet used for the ventilator is easily accessible; disconnection from the outlet is the only way to completely remove power from the ventilator.

To connect the power cord to AC power

1. Plug the ventilator into a properly grounded power outlet rated for at least 15 A.

2. Verify the connection by checking the AC indicator below the power switch on the front of the BDU. Reference *Ventilator Power Switch and AC Indicator*, p. 2-26 for the power switch and AC indicator locations.

To connect the power cord to the ventilator

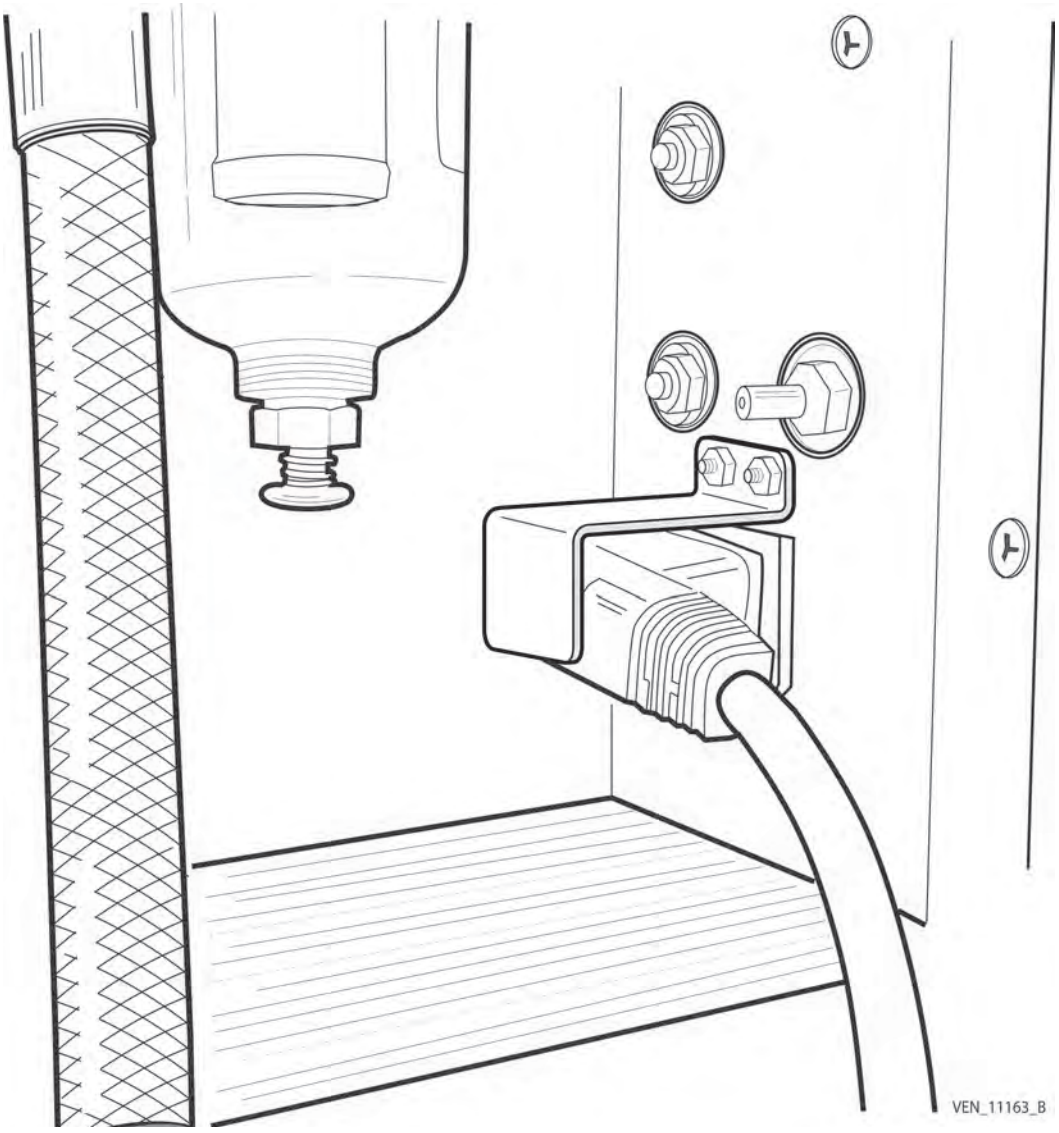
1. Remove the power cord retainer and connect the female end of the power cord to the ventilator's power cord receptacle. Reference *Power Cord Retainer on BDU*, p. 3-7.

2. Replace the power cord retainer.

Use the power cord hook located at the back of the ventilator for power cord storage.

WARNING:
For proper ventilator operation, and to avoid the risk of electric shock, connect the ventilator to a grounded, hospital grade, AC electrical outlet.

Figure 3-2. Power Cord Retainer on BDU



3.5.2 Connecting the Gas Supplies

The ventilator can be connected to hospital grade wall or bottled air and oxygen. Reference *Connecting the Ventilator to the Gas Supplies*, p. 3-9. Both air and O_2 supply pressure ranges must be between 35 and 87 psig (241.3 kPa to 599.8 kPa) and the average flow requirement for both gases is 60 L/min at 40.61 psi. The transient will not exceed 200 L/min for ≥ three (3) s.

WARNING:
Due to excessive restriction of the Air Liquide™, SIS, and Dräger™ hose assemblies, reduced ventilator performance levels may result when oxygen or air supply pressures < 50 psi (345 kPa) are employed.

Gas cross flow from one high pressure input port of one type of gas to another high pressure input port of a different gas will not exceed 100 mL/h under normal or single fault conditions. If, during a single fault condition, cross flow exceeds 100 mL/h, an audible alarm annunciates.

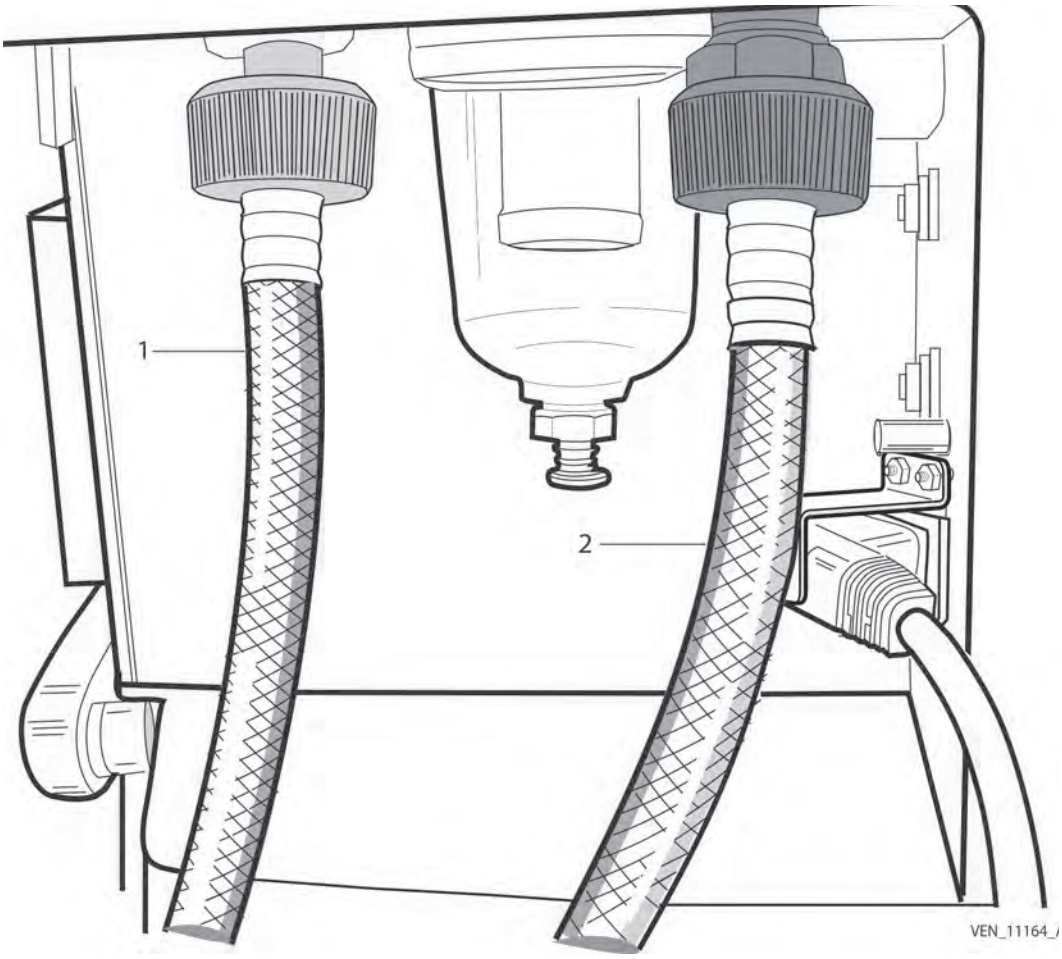
WARNING:
Use of only one gas source could lead to loss of ventilation and/or hypoxemia if that one gas source fails and is not available. Therefore, always connect at least two gas sources to the ventilator to ensure a constant gas supply is available to the patient in case one of the gas sources fails. The ventilator has two connections for gas sources: air inlet, and oxygen inlet. Reference *Non-technical Alarm Summary*, p. 6-18 for alarms that occur due to a loss of either gas supply.

To connect the gas sources

1. Connect the oxygen hose to the oxygen inlet fitting (item 1) as shown. Ensure use of a medical grade oxygen source.

2. Connect the air hose to the air inlet fitting (item 2) Reference *Connecting the Ventilator to the Gas Supplies*, p. 3-9.

Figure 3-3. Connecting the Ventilator to the Gas Supplies



1 O_2 gas connection

2 Air gas connection

WARNING:
To prevent a potential fire hazard and possible damage to the ventilator, ensure the connections to the gas supplies are clean and unlubricated, and there is no water in the supply gas. If water is suspected, use an external wall air water trap to prevent damage to the ventilator or its components.

The ventilator system can be purchased with the following gas inlet fittings for both air and O_2: BOC, DISS, female, NIST, Air Liquide, SIS, and Dräger.

Reference *Covidien Accessories and Options*, p. 9-4 for part numbers of gas hoses. For countries outside the USA, contact your local Covidien representative for the proper gas hoses.

3.5.3 Filter Installation

The ventilator is shipped with internal and external inspiratory filters. Reference *Covidien Accessories and Options*, p. 9-4 for the part numbers of expiratory filters. To prevent infection and contamination, both inspiratory and expiratory filters must be used with the ventilator.

WARNING:
In order to reduce the risk of infection, always use the ventilator with inspiratory and expiratory bacteria filters.

WARNING:
Do not attempt to use inspiratory or expiratory filters designed for use with ventilators other than the Puritan Bennett 980 Series Ventilator. Reference *Covidien Accessories and Options*, p. 9-4 for relevant part numbers.

WARNING:
Refer to the filter's instructions for use for details such as cleaning and sterilization requirements, filtration efficiency, proper filter usage, and maximum filter resistance, particularly when using aerosolized medications.

Caution:
Ensure both inspiratory and expiratory filters are properly attached to the ventilator.

To install the inspiratory filter

1. Attach the inspiratory filter to the **To Patient** port.
2. Ensure the direction of flow arrow is pointing outward, toward the patient circuit's inspiratory limb.

Note:
Refer to the inspiratory filter IFU for information on proper use and handling of the filter.

WARNING:
Refer to the expiratory filter instructions for use (IFU) for information on reusable filter cleaning and sterilization and filter efficiency.

Note:
Refer to the expiratory filter IFU for information on proper use and handling of the filter and for emptying the condensate vial for adult and pediatric patients. *Reference Appendix E* for information on emptying the condensate vial when using neonatal expiratory filters.

WARNING:
Do not re-use disposable inspiratory or expiratory filters, and dispose according to your institution's policy for discarding contaminated waste.

The condensate vial must be assembled to the reusable expiratory filter prior to installing the assembly to the ventilator.

To assemble the Adult/Pediatric reusable expiratory filter and condensate vial

1. Seat the filter to the condensate vial, ensuring alignment of the condensate vial's seal with the mating edge of the expiratory filter.
2. Twist the condensate vial in a counterclockwise direction until the stops on the vial and expiratory filter meet.

To install the Adult/Pediatric expiratory filter

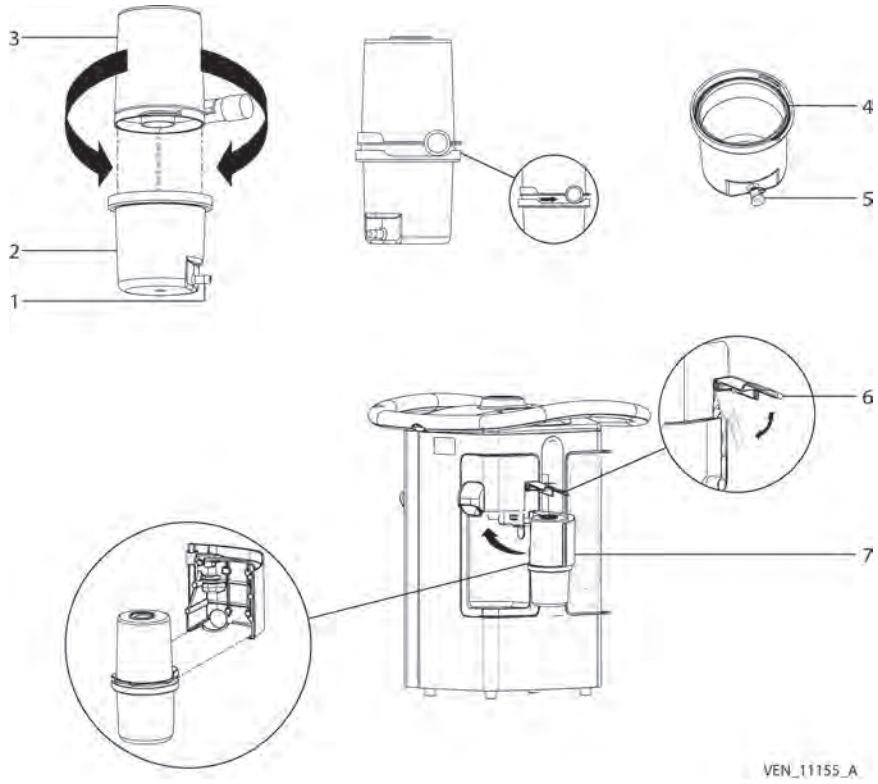
1. If necessary, remove expiratory limb of patient circuit from expiratory filter.



2. Raise the expiratory filter latch to unlock (item 6).Reference *Adult/Pediatric Filter Installation*, p. 3-12. This raises the exhalation valve assembly and allows the filter door to swing away from the ventilator.
3. Open the expiratory filter door.
4. Remove the existing filter.
5. Insert the new filter by sliding the filter along the tracks in the door. Ensure the **From Patient** port aligns with the cutout in the door and points away from the ventilator.
6. Close the expiratory filter door.
7. Lower the expiratory filter latch to secure the filter.

WARNING:
Do not operate the expiratory filter latch during patient ventilation. Opening the latch during ventilation will result in a patient disconnect condition and corresponding alarm.

Figure 3-4. Adult/Pediatric Filter Installation



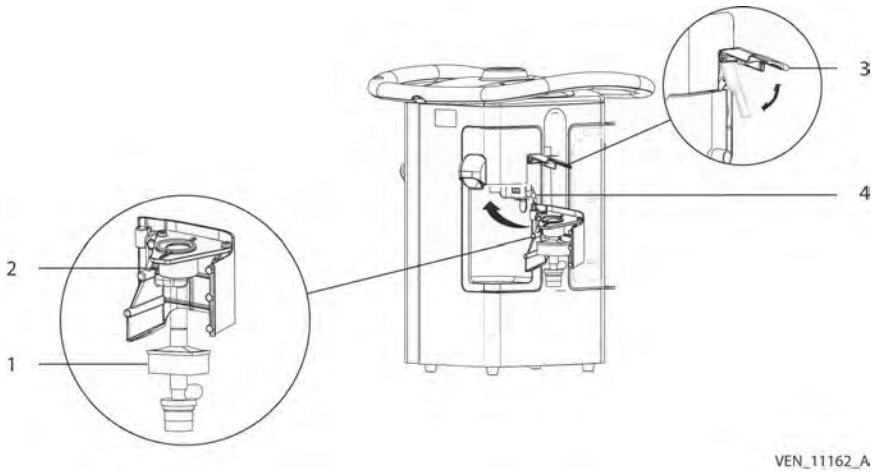
1	Condensate drain port	5	Condensate drain port cap
2	Condensate vial	6	Expiratory filter latch
3	Expiratory filter	7	Expiratory filter door
4	Condensate vial gasket		

To install the neonatal expiratory filter adapter door

1. If necessary, remove expiratory limb of patient circuit from expiratory filter.
2. Lift expiratory filter latch. Reference *Installing the Neonatal Filter*, p. 3-13 (item 3).
3. Remove existing expiratory filter door by lifting it off of the pivot pins.

4. Fit neonatal adapter door onto pivot pins.

Figure 3-5. Installing the Neonatal Filter



1	Neonatal expiratory filter	3	Expiratory filter latch
2	Neonatal adapter door	4	Filter door pivot pin

Note:
Unlike the pediatric/adult expiratory filter and condensate vial, the neonatal filter and condensate vial assembly is provided assembled. The condensate vial is removable for discarding accumulated liquid, by turning the vial clockwise to remove and counterclockwise to install.

To install the neonatal expiratory filter assembly

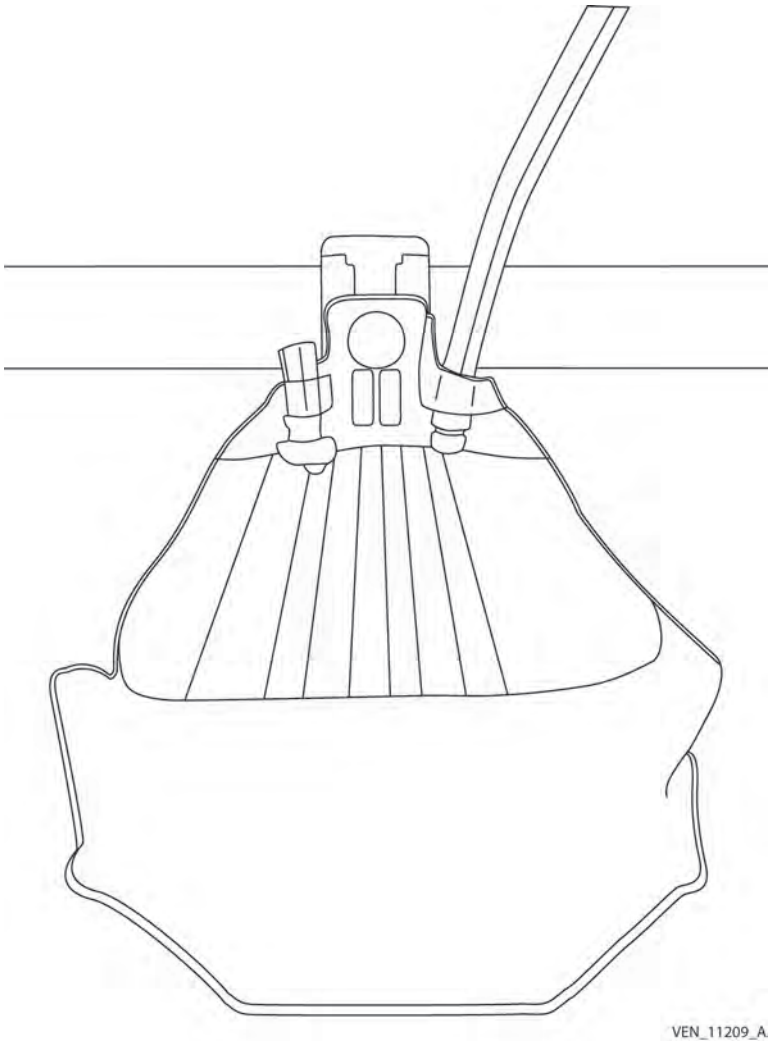
1. With the door still open, push the neonatal filter assembly straight up into the adapter.
2. Close the door.
3. Lower the expiratory filter latch.
4. Re-attach expiratory limb of patient circuit to filter.

To use the drain bag

1. Remove the drain port cap from the expiratory filter condensate vial drain port.
2. Attach the drain bag tube to the condensate vial's drain port.

3. Hang the drain bag on the holder located on the ventilator's accessory rail, as shown below. Reference *Covidien Accessories and Options*, p. 9-4 for part number of drain bag holder.

Figure 3-6. Drain Bag



3.5.4 Connecting the Patient Circuit

Reference *Connecting the Adult or Pediatric Patient Circuit*, p. 3-16 or Reference *Connecting the Neonatal Patient Circuit*, p. 3-17 to connect the adult, pediatric, or neonatal patient circuits.

WARNING:
Use patient circuits of the lowest compliance possible with the ventilator system to ensure optimal compliance compensation and to avoid reaching the safety limit of five times set tidal volume or the compliance compensation limit. Reference the table below for circuit types corresponding with predicted body weight (PBW).

Table 3-1. Patient Types and PBW Values

Circuit Type	PBW in kg (lb)	Allowed but not recommended
Neonatal	0.3 kg to 7.0 kg (0.66 to 15 lb)	Not applicable
Pediatric	7.0 kg to 24 kg (16 lb to 53 lb)	3.5 kg to 6.9 kg and 25 kg to 35 kg (7.7 lb to 15 lb and (55 lb to 77 lb)
Adult	25kg to 150 kg (55 lb to 331 lb)	7.0 kg to 24 kg (16 lb to 53 lb)

Note:
Refer to the patient circuit's instructions for use (IFU) for information on proper use and handling and care and maintenance of the circuit.

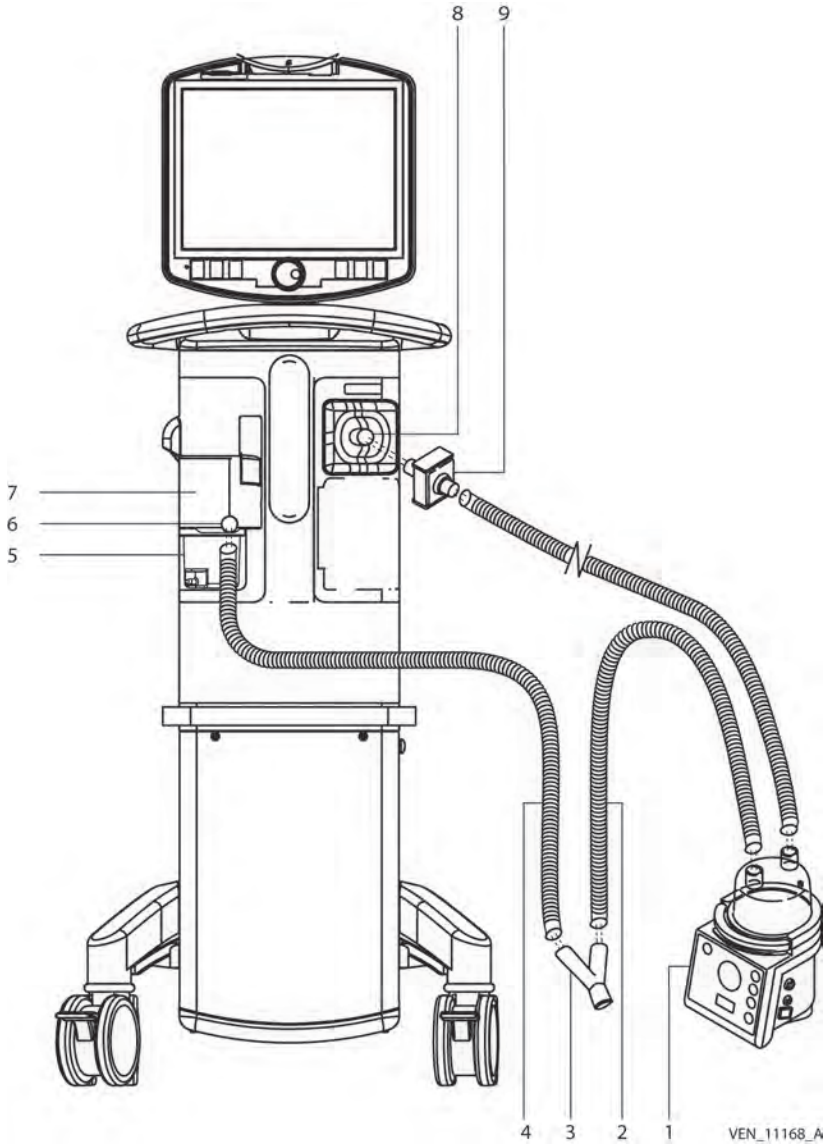
A list of breathing system components and accessories is provided. Reference *Covidien Accessories and Options*, p. 9-4. Use only Covidien- components and accessories in the patient circuit.

Follow your institution's protocol for safe disposal of the patient circuit.

Follow the patient circuit's instructions for use (IFU) for cleaning and disinfection information for reusable circuits.

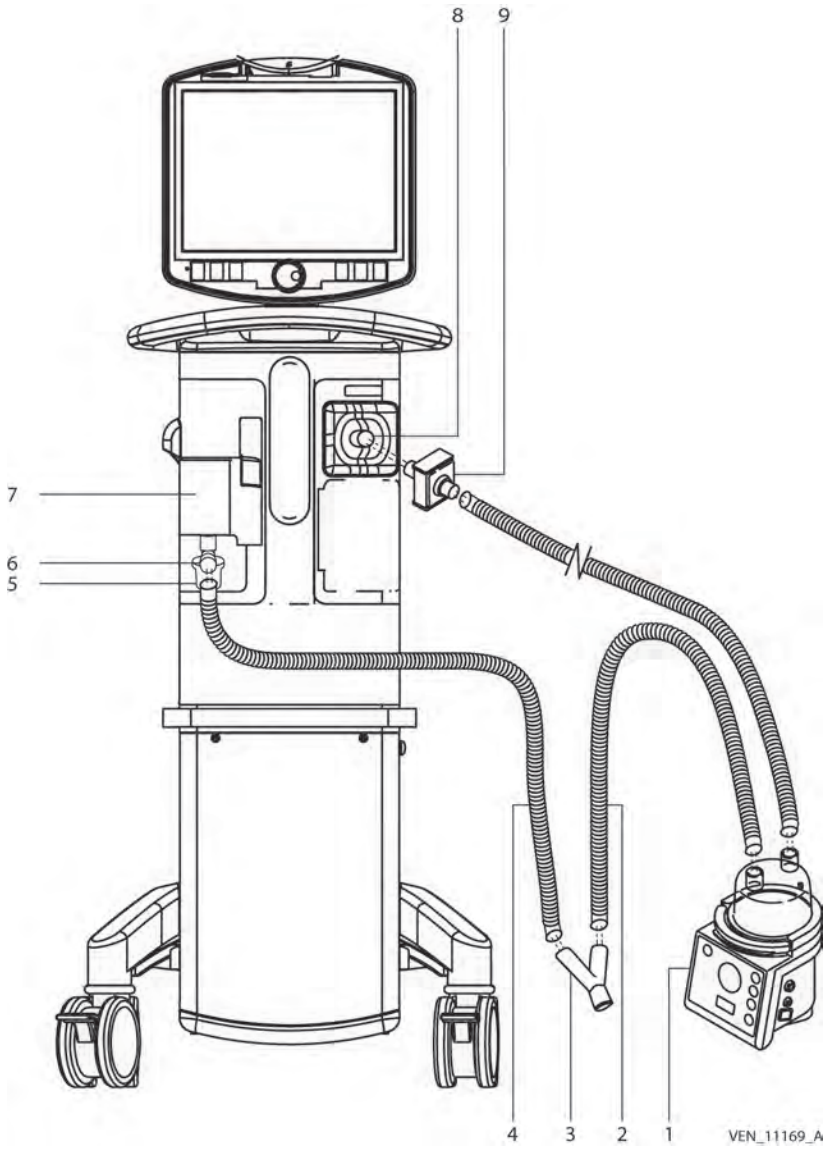
Orient the patient circuit by hanging the patient circuit on the circuit management supports provided with the flex arm.

Figure 3-7. Connecting the Adult or Pediatric Patient Circuit



1	Humidifier	6	From Patient port
2	Inspiratory limb	7	Expiratory filter
3	Circuit wye	8	To Patient port
4	Expiratory limb	9	Inspiratory filter
5	Condensate vial		

Figure 3-8. Connecting the Neonatal Patient Circuit



1	Humidifier	6	From patient port
2	Patient circuit inspiratory limb	7	Neonatal expiratory filter (installed in adapter door)
3	Circuit wye	8	To patient port
4	Patient circuit expiratory limb	9	Inspiratory filter
5	Condensate vial		

WARNING:
Do not attempt to sterilize single-patient use circuits.

3.6 How to Install Accessories

3.6.1 Batteries

WARNING:
Use only Covidien-branded batteries. Using other manufacturer's brands or remanufactured batteries could result in the batteries operating the ventilator for less than the specified amount of time or could cause a fire hazard.

WARNING:
To reduce the risk of infection due to cross-contamination, using a damp cloth, disinfect the batteries with one of the solutions listed before installation and whenever transferring to or from another ventilator. During use, clean external surfaces of batteries as necessary. Reference *Surface Cleaning Agents*, p. 7-5. Do not spray disinfectant directly onto the battery or its connector. Reference *Ventilator Battery*, p. 3-19 (item 1).

Caution:
Ensure the batteries are oriented properly. Reference *Proper Battery Orientation*, p. 3-20.

Figure 3-9. Ventilator Battery



1 Battery connector

Primary Batteries

The ventilator's primary battery is located in the rearward battery receptacle on the right side of the BDU. Reference *Battery Compartment Locations*, p. 3-21. The primary battery may be "hot swapped," that is it can be replaced while the ventilator is operating.

To install or replace the primary battery in the BDU

1. With the battery not installed in the ventilator, or if the ventilator is turned off and not connected to AC power, check the charge level by pressing the charge level button on the battery and verifying the charge level LEDs illuminate. Reference *Proper Battery Orientation*, p. 3-20. for the location of the charge level button. Five green LED segments illuminate, indicating ≥ 90% battery capacity. From bottom to top, the first LED indicates ≥ 10% capacity, the second LED indicates ≥

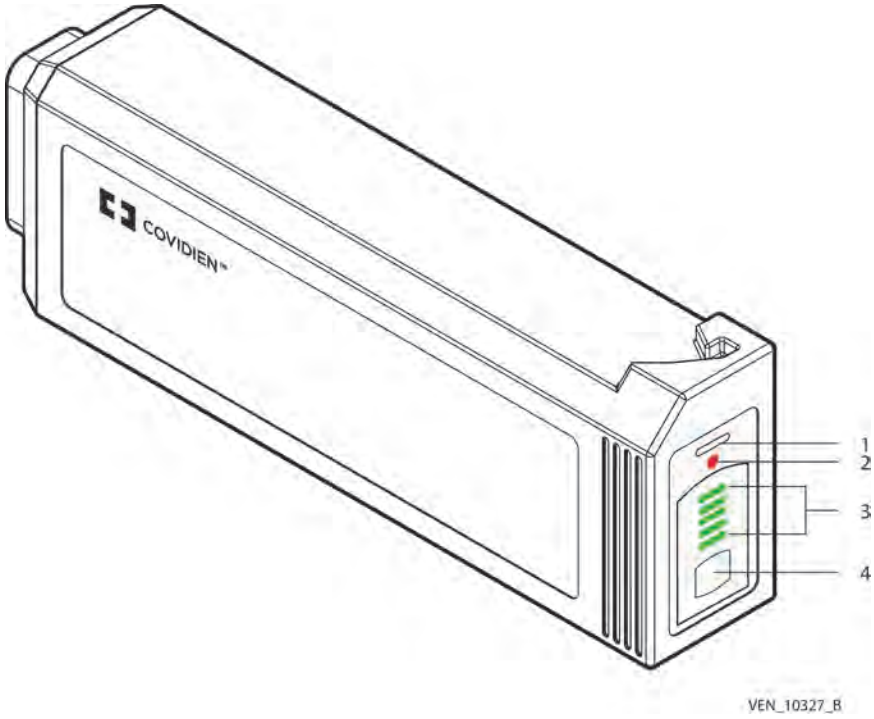
25% capacity, the third LED indicates ≥ 50% capacity, and the fourth LED indicates ≥ 75% capacity. An illuminated red LED at the top of the battery indicates a battery fault. If no LEDs illuminate it means there is < 10% battery capacity remaining.

2. If the charge level is sufficient, orient the battery as shown, Reference *Proper Battery Orientation*, p. 3-20, face the front of the ventilator and locate the battery compartments on the right side of the BDU. Reference *Battery Compartment Locations*, p. 3-21. The receptacle towards the rear of the ventilator houses the primary battery while the receptacle towards the front of the ventilator houses the extended battery.

3. The primary battery is fastened in place with a thumbscrew (item 3). Loosen the thumbscrew approximately four to five turns to allow battery installation.

4. Insert the battery and push into its receptacle all the way until it clicks, indicating it is latched. The battery will only fit into the slot one way.

Figure 3-10. Proper Battery Orientation

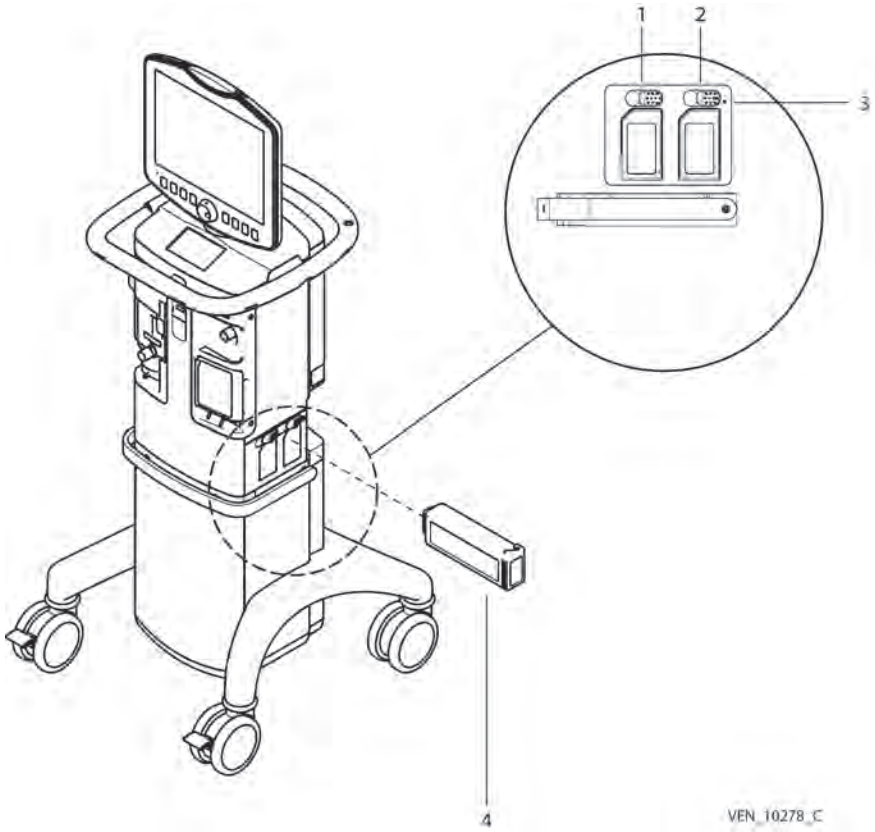


1	White battery in-use LED	3	Green charge status LEDs
2	Red battery fault indicator	4	Charge level button

5. Tighten the thumbscrew to secure the battery and prevent the primary battery from being removed.

Note:
Remove the primary battery by reversing the steps. After loosening the thumbscrew, slide the battery ejector to the left to eject the battery.

Figure 3-11. Battery Compartment Locations



1	BDU extended battery receptacle and battery ejector	3	BDU primary battery thumbscrew
2	BDU primary battery receptacle and battery ejector	4	BDU primary battery (positioned for installation)

Extended batteries

The extended battery receptacle is located forward of the primary battery. Like the primary battery, the extended battery may be hot swapped.

To install or remove an extended battery in the BDU

1. Properly orient the battery as shown above.
2. Push the battery into the forward receptacle in the BDU all the way until it clicks, indicating the battery is latched. Reference *Battery Compartment Locations*, p. 3-21.

Note:
Remove the battery by sliding the battery ejector to the left. The battery ejects itself from its receptacle. There is no thumbscrew for extended batteries.

WARNING:
Even though the Puritan Bennett 980 Ventilator meets the standards listed in *Chapter 11*, the internal Lithium-ion battery of the device is considered to be Dangerous Goods (DG) Class 9 - Miscellaneous, when transported in commerce. As such, the Puritan Bennett 980 Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements may apply.

WARNING:
To avoid the risk of fire, explosion, electric shock, or burns, do not short circuit, puncture, crush, heat above 60°C, incinerate, disassemble the battery, or immerse the battery in water.

Note:
Reference *Battery Charging*, p. 3-4 for battery charging information when batteries are installed in ventilator.

3.6.2 Battery Testing

To test the batteries

1. Push the battery charge level button located on the battery. A series of LEDs illuminates, indicating the charge level of the battery. When the bottom LED is illuminated, there is ≥ 10% of full battery capacity. The next LED illuminates when there is ≥ 25% capacity. the third lamp illuminates when there is ≥ 50% capacity available. The fourth LED illuminates when there is ≥ 75% capacity, and when the top LED is illuminated, it represents ≥ 90% capacity. Reference *Proper Battery Orientation*, p. 3-20 to view the battery test button and LEDs.

3.6.3 Battery Performance Test Results

Performance testing on a sample of new batteries and batteries charged and discharged at least 1000 times was completed to demonstrate that the ventilator's LOW BATTERY alarms remain effective. Testing demonstrated that the batteries have a minimum of ten (10) minutes time remaining from the activation of the low battery alarm and a minimum of five (5) minutes time remaining from the critically low battery alarm until ventilator shutdown. Reference *Status Display Indicators and Descriptions*, p. 2-30 for images of the Status Display during low battery and critically low battery conditions.

Performance testing on a sample of new batteries and batteries charged and discharged at least 1000 times was completed to demonstrate the expected run time of the ventilator on battery. This testing was performed for both typical ventilator settings and adult high demand ventilator settings.

The typical ventilator settings used were:

- Ventilator settings
  - Assist/Control Ventilation with Volume Control (VC) mandatory type
  - Tidal volume (V_T) = 500 mL
  - Peak flow ($\dot{V}_{MAX}$) = 30 L/min
  - Respiratory rate (f) = 20 1/min
  - PEEP = 8 cmH_2O
  - Oxygen concentration (FiO_2) = 60%
  - Flow trigger ($\dot{V}_{-TRIG}$) = 3 L/min

- Approximate respiratory monitored parameters during simulation
  - Peak pressure (P_{PEAK}) = 27 cmH_2O
  - Plateau pressure (P_{PL}) during manual inspiratory pause = 23 cmH_2O
  - Exhaled tidal volume (V_{TE}) 442 mL (BTPS)
  - Total respiratory rate (R_{TOT}) = 20 1/min
  - I:E ratio = 1:2
  - PEEP = 8 cmH_2O / Total PEEP ($PEEP_{TOT}$) during expiratory pause = 8 cmH_2O
  - Exhaled minute volume ($\dot{V}_{ETOT}$) = 8.84 L/min
- Adult high-demand ventilator settings
  - Assist/Control Ventilation with Pressure Control (PC) mandatory type
  - Inspiratory pressure (P_I) = 55 cmH_2O
  - Inspiratory time (T_I) = 0.55 s
  - Respiratory rate (*f*) = 60 1/min
  - PEEP = 35 cmH_2O
  - Oxygen concentration (FiO_2) = 60%
  - Flow trigger ($\dot{V}_{-TRIG}$) = 20 L/min
- Approximate respiratory monitored parameters during adult high-demand simulation
  - Peak pressure (P_{PEAK}) = 90 cmH_2O
  - Plateau pressure (P_{PL}) during manual inspiratory pause = 79 cmH_2O
  - Exhaled tidal volume (V_{TE}) 900 mL (BTPS)
  - Total respiratory rate (R_{TOT}) = 60 1/min
  - I:E ratio = 1:1

- PEEP = 39 cmH_2O / Total PEEP ($PEEP_{TOT}$) during expiratory pause = 49 cmH_2O
- Exhaled minute volume ($\dot{V}_{ETOT}$) = 52 L/min

The run time does not vary significantly between typical and heavy load settings. The ventilator can be expected to run approximately 75 minutes at typical settings with new batteries. When running batteries nearing end of life (batteries with 1000 charge/discharge cycles were used for this data) the run time can be expected to be approximately 55 minutes.

3.6.4 Battery Life

Battery life for both primary and extended batteries is approximately three (3) years. Actual battery life depends on the history of use and ambient conditions. As the batteries age with use, the time the ventilator will operate on battery power from a fully charged battery will decrease. Replace the battery every three (3) years or sooner if battery operation time is insufficient for your usage.

3.6.5 Battery Disposal

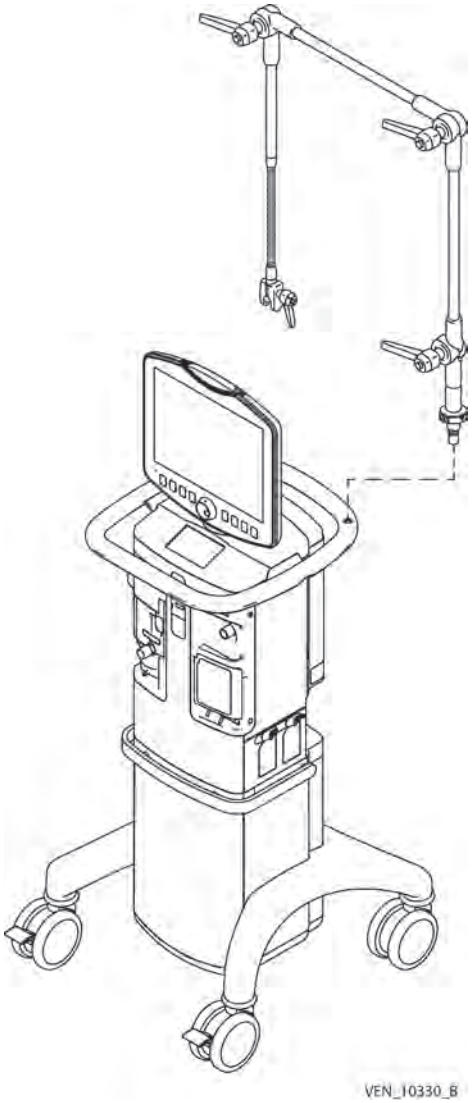


The battery is considered electronic waste and must be disposed of according to local regulations. Follow local governing ordinances and recycling plans regarding disposal or recycling of the battery.

3.6.6 Flex Arm

Use the flex arm to support the patient circuit between the patient and the ventilator. Reference *Flex Arm Installation*, p. 3-26, which illustrates flex arm installation into the sockets provided.

Figure 3-12. Flex Arm Installation



To attach or remove the flex arm

1. Locate the threaded inserts in the ventilator's handle.
2. Fasten the flex arm into one of the inserts.
3. Hang the patient circuit using the circuit management supports included with the flex arm.
4. Remove the flex arm by first removing the patient circuit, then un-fastening the flex arm from the threaded fastener in the handle.

3.6.7 Humidifier

Use the humidifier to add heat and moisture to the inhaled gas. Connect the humidifier to a hospital grade electrical outlet. Choose the humidifier (type and volume appropriate for the patient). The humidifier may be mounted with the humidifier bracket as shown. Reference *Covidien Accessories and Options*, p. 9-4 for the part number of the humidifier bracket.

WARNING:
Selection of the incorrect humidifier type and/or volume during SST or during patient ventilation can affect the accuracy of delivered volume to the patient by allowing the ventilator to incorrectly calculate the compliance correction factor used during breath delivery. This can be a problem, as the additional volume required for circuit compressibility compensation could be incorrectly calculated, resulting in over- or under-delivery of desired volume.

WARNING:
To ensure proper compliance and resistance calculations, perform SST with the humidifier and all accessories used for patient ventilation installed in the ventilator breathing system.

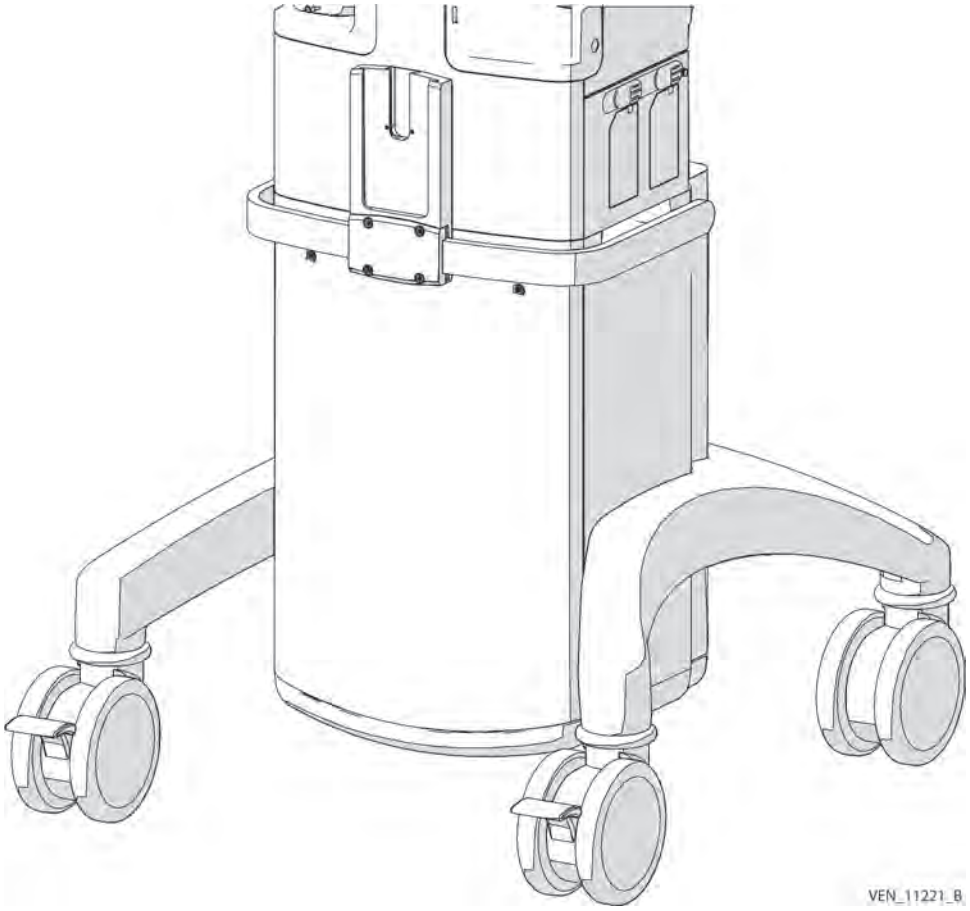
WARNING:
Follow the humidifier manufacturer's Instructions for Use (IFU) when using a humidifier with patient ventilation.

Caution:
Follow humidifier manufacturer's instructions for use (IFU) for proper humidifier operation.

To install the humidifier bracket

1. Attach humidifier bracket to the ventilator's accessory rail by placing the bracket behind the railing and fastening the bracket clamp to the bracket with four (4) 5/32 inch hex screws, capturing the railing between the bracket and the clamp. Ensure the humidifier mounting slots are facing outward from the ventilator.

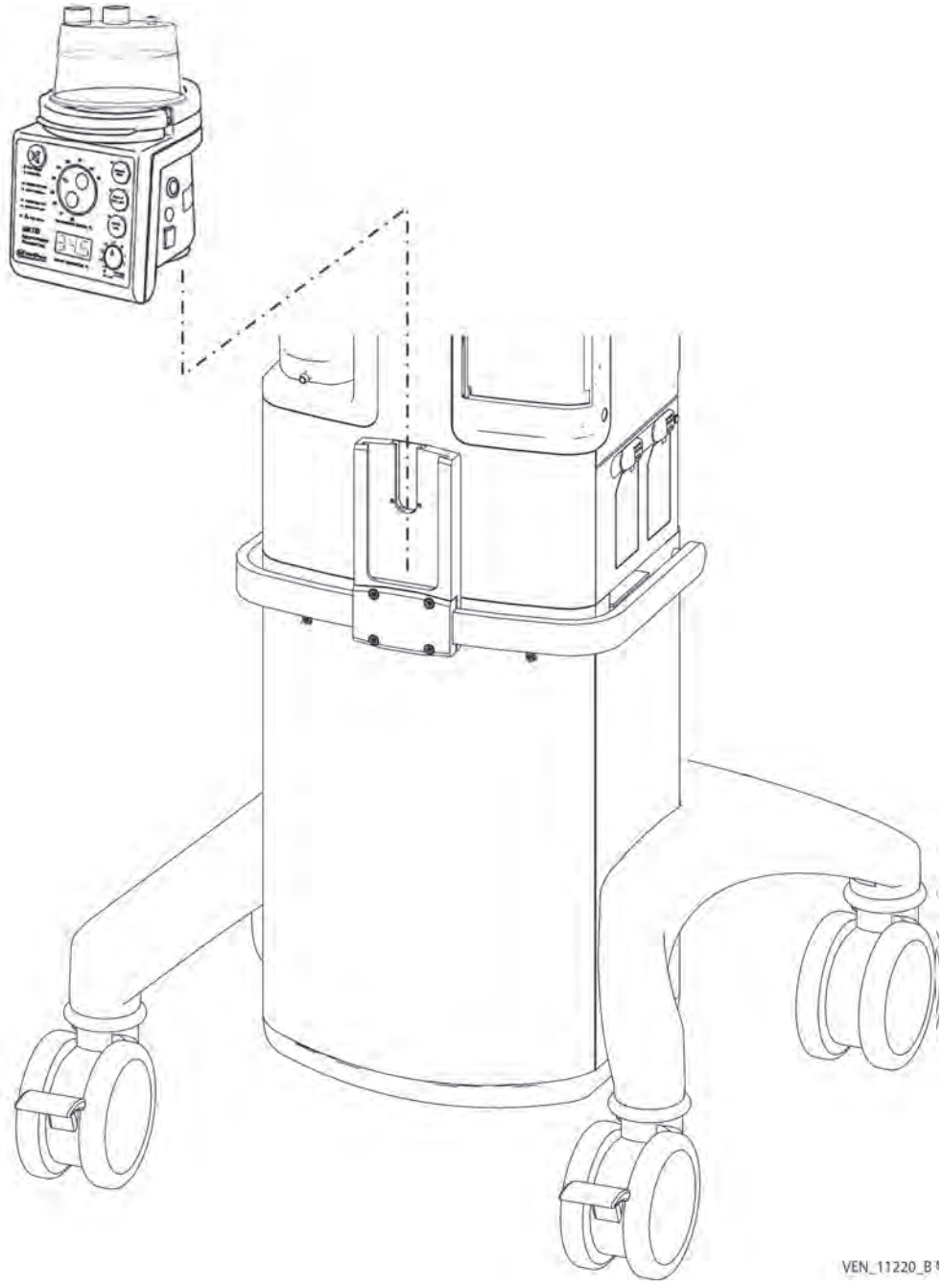
Figure 3-13. Bracket Installation on Rail



To install the humidifier

1. Slide the rear of the humidifier into the corresponding slot on the humidifier bracket, until it is fully seated. Reference *Humidifier Installation to Ventilator*, p. 3-29. Some humidifiers slide into the narrow slot in the humidifier bracket, and some humidifiers use the wide slot.

Figure 3-14. Humidifier Installation to Ventilator



2. Fill the humidifier with water to the desired fill volume.
3. Install the chamber to the humidifier, connect the patient circuit, then run SST.

4. Plug the humidifier into a grounded, hospital grade electrical outlet.

5. Turn the humidifier on.

Note:
Complete instructions for the humidifier bracket and humidifier installation are given in the Puritan Bennett™ 980 Series Ventilator*Humidifier Bracket Installation Instructions*, which includes humidifier bracket part numbers and descriptions.

3.7 Ventilator Operating Modes

3.7.1 Normal Mode

Normal mode is the default mode used for patient ventilation. The ventilator enters Normal mode after it has been turned on and POST completes, the ventilator is set up, and breath delivery parameters have been entered. If the clinician chooses, s/he can select Quick Start which uses default values or institutionally configured breath delivery settings after PBW has been entered. Entry into Normal mode is not allowed if a primary battery is not detected in the ventilator BDU, a major POST fault occurs, or there is an uncorrected major system fault, or uncorrected ***Short Self Test (SST)*** or ***Extended Self Test (EST)*** failures or non-overridden alerts.

During Normal mode, the omni-directional LED on the top of the GUI appears green in color, in a steadily lit state. If an alarm occurs, the LED flashes in a color corresponding to the priority of the alarm. Reference *Alarm Prioritization*, p. 6-16 for details regarding alarm priority. If another alarm occurs concurrently with an existing alarm, the LED displays the color corresponding to the highest priority level. If the alarm de-escalates, the latched area (located on either side of the alarm LED indicator) of the alarm LED displays the color of the highest priority alarm while the center of the LED displays the color of the current alarm's priority. For more information on specific alarms, touch the logs icon in the constant access icons area of the GUI.

3.7.2 Quick Start

Quick Start is an extension of Normal mode, where institutionally configured default settings are applied after the patient's PBW or gender and height are entered and *Quick Start* is touched to begin ventilation.

3.7.3 Stand-By State

Stand-By state can be used when the clinician needs to disconnect the patient for any reason (prior to a suction procedure, for example). The ventilator enters Stand-By state if a request is made by the clinician, a patient is disconnected within a fixed time period determined by the ventilator software, and the clinician confirms the patient has been disconnected intentionally. If a patient becomes disconnected from the patient circuit after the time period elapses, an alarm sounds and the patient-disconnect sequence is initiated. In Stand-by state, gas output is reduced to ten (10) L/min to limit gas consumption and to allow for detection of patient reconnection, and O_2 concentration becomes 100% for adult and pediatric circuit types and 40% for neonatal circuit types. Stand-by state is available in all ventilation modes except during Inspiratory and Expiratory ***BUV***, ***Occlusion Status Cycling (OSC)***, **Safety Valve Open (SVO)**, or Ventilator **Inoperative (Vent Inop)** conditions.

Note:
Do not block patient circuit wye while in Stand-By state. If the wye is blocked, the ventilator detects a patient connection and will attempt to resume normal ventilation.

To enter Stand-By state

1. Touch the Menu tab on the left side of the GUI. The menu appears.
2. Touch *Stand-By*. A Stand-By state pending dialog appears instructing the clinician to disconnect the patient circuit. A timer starts which allows 30 *s* to disconnect the patient.
3. Disconnect the patient circuit and confirm the disconnection by touching *Confirm*. A timer starts which allows 30 *s* for confirmation of disconnect.

To exit Stand-by state

1. Reconnect the patient circuit. The ventilator resumes ventilation at the settings in use before the disconnection.

The following ventilator settings become active during Stand-by state:

- Base flow is set to ten (10) L/min
- 100% O_2 for adult/pediatric patients
- 40% O_2 for neonatal patients

During Stand-by state

- The exhalation valve is open.
- Current ventilator settings are retained in memory.
- Flow sensors are monitored to detect patient reconnection.
- Patient-related alarms are temporarily suppressed, as described below.
- Ventilator settings can be changed, if desired, and will be applied upon patient reconnection.
- The ventilator displays an indicator that it is in Stand-by State, and a timer indicating the elapsed time the ventilator has been in Stand-by state.
- Ventilator background checks continue to be made.

The ventilator automatically exits Stand-by state when patient reconnection is detected, the clinician completes patient setup (if ventilation was mistakenly started before setup was complete), or the ventilator power is cycled.

Prior to entering Stand-by state, the ventilator measures pressure and flow in the patient circuit to determine if a patient is attached. If a patient is detected, the ventilator continues ventilation as set prior to the request, alerts the operator that Stand-by state is pending, and requests the patient be disconnected. A countdown timer appears alerting the operator of the time remaining to disconnect the patient. After the patient is disconnected, the ventilator requests confirmation of the disconnection. When the ventilator enters Stand-by state, a message appears on the GUI, any active alarms are silenced and reset and the associated alarm reset entries are logged in the Alarm Event Log. Alarm detection is suspended, and breath delivery is suspended while a bias flow is maintained for patient detection. During Stand-by state, the ventilator displays the elapsed time the patient has been without ventilation. Since the ventilator maintains a bias flow for patient detection, it resumes ventilation at the previous settings when the patient is reconnected. There is no need to touch *Exit Stand-By*. Reconnecting the patient returns the ventilator to normal operation. During Stand-by state, patient data values are not displayed and the LED located at the top of the GUI cycles between yellow and green. Entry into and exit from Stand-by state is recorded in the General Event log.

3.7.4 Service Mode

WARNING:
Before entering Service Mode, ensure a patient is not connected to the ventilator. Ventilatory support is not available in Service Mode.

Service Mode is used for Extended Self Test (EST), ventilator calibration, configuration, software upgrades, option installation (all of which must be performed by Covidien factory-trained service personnel), and for making adjustments to institutional settings. All information stored in the individual logs is available in Service Mode. Service Mode logs include:

- System diagnostic Log
- System Comm. Log
- EST/SST Diagnostic log
- Settings Log
- Alarms Log
- General Event Log
- Service log
- Patient data Log

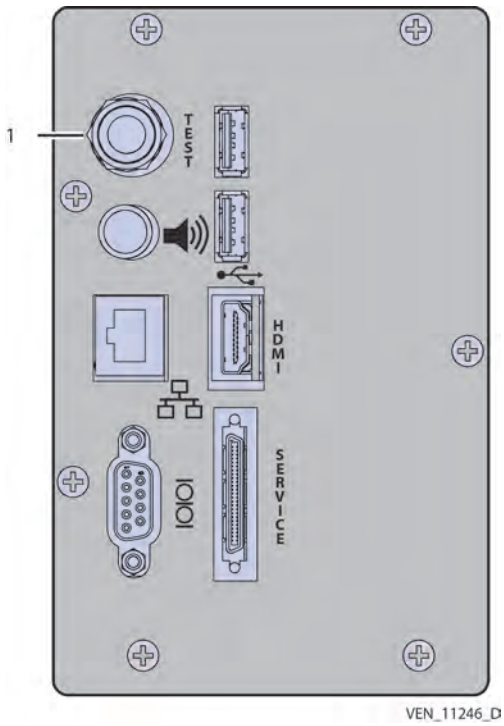
Reference the Puritan Bennett™ 980 Series Ventilator *Service Manual* for details about Service Mode logs.

A patient must not be attached to the ventilator when entering Service Mode. Specific actions must be performed to enter this mode, prior to POST completion.

To access Service Mode

1. Remove the ventilator from patient usage.
2. Turn the ventilator's power switch ON.
3. Press and release the Service Mode button (TEST) at the back of the ventilator, when the Covidien splash screen appears on the status display after powering on the ventilator. Reference *Service Mode Button (TEST)*, p. 3-34. Reference *Status Display Indicators and Descriptions*, p. 2-30 for an image of the splash screen. The ventilator prompts to confirm no patient is attached.

Figure 3-15. Service Mode Button (TEST)



1 Service Mode button

4. Wait to enter Service Mode.
5. Confirm a patient is not connected to the ventilator by touching the corresponding button. The message SERVICE MODE VENTILATION SUPPORT IS NOT AVAILABLE appears on the graphical user interface.
6. Perform required service.
7. Touch *Exit* or turn off the ventilator to exit Service Mode.

Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* for information on which keys are disabled during EST.

In addition to allowing SST to be run, Service Mode also allows configuration of various items. Reference *Ventilator Configuration*, p. 3-35 for a list of institutionally- and operator-configurable items.

3.8 Product Configuration

The ventilator is shipped configured with factory defaults for new patient parameters which can be configured to suit institutional preferences. The operator may configure any desired parameter as long as this option has not been locked out and rendered unavailable. When configuring the ventilator, it displays the parameters associated with the operator's last configuration. The following table lists the factory-configured settings, the institutionally-configurable settings, and the operator-configurable settings.

WARNING:
If the ventilator fleet in your institution uses multiple institutionally configured presets and/or defaults, there can be risks of inappropriate alarm settings.

Table 3-2. Ventilator Configuration

Feature	Factory Configured	Institutionally Configurable	Operator Configurable	Configured by Circuit Type	User Lockable
Vital patient data banner	X	X	X		X
Large font patient data panel	X	X	X		X
Waveform layout	X	X	X		X
Display brightness (Light settings)	X	X	X		
Alarm volume	X	X	X	X	
Elevate O_2 control	X	X	X	X	
Date/time format	X	X	X		X
Default mL/kg ratio	X	X			Can't be changed in Normal mode

Table 3-2. Ventilator Configuration

Feature	Factory Configured	Institutionally Configurable	Operator Configurable	Configured by Circuit Type	User Lockable
New patient startup defaults (including PBW, vent type, mode, mandatory type, trigger type, O_2%, elevate O_2)	X	X		X	
Opacity	X	X	X		X

3.8.1 Preparing the Ventilator for Use

Caution:
Do not lean on the GUI or use it to move the ventilator. Doing so could break the GUI, its locking mechanism, or tip the ventilator over.

Prior to ventilating a patient, configure the GUI so it is capable of displaying all the desired parameters, information, and patient data. This eliminates the necessity for taking the patient off the ventilator, as configuration of many of the items requires the unit to be in Service Mode.

To perform institutional configuration

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.
2. Touch *Configuration* at the top of the screen in Service Mode. A list of buttons appears allowing configuration of the corresponding parameters.
3. Reference the sections below for specific instructions on institutional configuration of each parameter.

To return to factory default configuration

1. Enter Service mode, and confirm no patient is attached by touching *Confirm*. Reference *Service Mode*, p. 3-33, for instructions on entering Service Mode.
2. Touch *Configuration* at the top of the screen in Service Mode. A list of buttons appears allowing configuration of the corresponding parameters.
3. Select the desired modified setting from the left-hand menu options.
4. Touch *Default*.

3.8.2 Configuring the GUI

The display can be configured in various ways.Reference *Ventilator Configuration*, p. 3-35 for the parameters which are factory configured, institutionally-configurable and operator-configurable. Once the factory or institutionally configurable items have been configured, they remain the default values. Factory configured values cannot be changed, however, if the parameters listed in the referenced table are institutionally configured, then those values remain in memory as default settings. If changes are made to operator-config-

urable parameters, they remain in memory during a ventilator power cycle as long as the same patient is set up when returned to ventilation. If a new patient is set up, the factory configured values or institutionally-configured values (if the parameter has been configured) are used. No alarm settings are institutionally configurable, which prevents changes to factory default alarm settings. However, the default mL/kg ratio is institutionally configurable, which can affect the default alarm setting values. Always review the alarm defaults prior to beginning ventilation, and set appropriately.

Date and Time Format

The date and time may be configured to the institution's preference. The time can be specified as 12-hour or 24-hour time in HH:MM:SS format with one-hour and one-minute resolutions, respectively. The date formats are:

- DD-MMM-YYYY where DD is a two-digit day format, MMM is a three-letter abbreviation for the month, and YYYY is a four-digit representation of the year or
- MM-DD-YYYY where MM is a two digit month format, DD is a two-digit day format, and YYYY is a four-digit representation of the year

The settable date corresponds to the number of days in the set month and accounts for leap years.

To institutionally configure the ventilator's date and time settings

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.
2. Touch *Date and Time*.
3. Touch the button corresponding to 12-hour or 24-hour time.
4. Touch *Hour* and turn the knob to enter the correct hour.
5. Repeat for the minutes, and am or pm.
6. Touch the button corresponding to the date format desired (DD-MM-YYYY or MM-DD-YYYY).
7. Touch *Accept* to confirm the date and time.
8. If done configuring parameters, exit Service Mode.

Pressure Units

The ventilator's pressure units can be configured for hPa or cmH_2O.

To institutionally configure pressure units

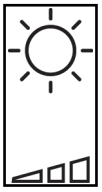
1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.
2. Touch *Vent Setup*.
3. Touch the button corresponding to the desired pressure units.
4. If done configuring parameters, exit Service Mode by touching *Exit*.

Screen Brightness and Keyboard Backlight (Light Settings)

To institutionally configure screen brightness and keyboard backlight

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.
2. Touch *Light Settings*. Sliders appear to adjust the screen brightness and keyboard backlight.
3. Move the sliders to increase or decrease the brightness and backlight levels. Alternatively, turn the knob to increase or decrease the brightness and backlight levels.
4. Touch *Accept* to apply the changes, or *Cancel* to revert to original settings.
5. If done configuring parameters, exit Service Mode.

To adjust display brightness



1. Press the display brightness key.
2. Slide the brightness slider or turn the knob to adjust the brightness level.
3. Dismiss the slider by touching anywhere on the GUI screen or allow to time out in five (5) *s*.

New Patient Setup Defaults

To institutionally configure new patient default settings

4. Touch the button corresponding to adult, pediatric, or neonatal New Patient Defaults.
5. Touch the *Vent type*, *Mode*, *Mandatory type*, and *Trigger type* buttons corresponding to the desired parameters.
6. Configure the default PBW and mL/kg ratio, Elevate O_2 and O_2% by touching its button and turning the knob.
7. Repeat for each patient type by selecting the corresponding button.
8. Touch *Accept* or *Accept ALL* when the default configuration is complete.
9. If done configuring parameters, exit Service Mode.

Elevate O_2

Note:
The Elevate O_2 control adds a percentage of O_2 to the breathing mixture for two minutes. The additional percentage is shown on the icon in the constant access icon area. The allowable range is 1% to 100%.

To adjust the amount of elevated O_2 delivered for two minutes

1. In the vent setup dialog in Normal mode, touch the Elevate O_2 icon in the constant access icons area of the GUI screen. The icon glows and a dialog appears with a countdown timer, *Elev* O_2 button highlighted and ready for changes, and *Extend*, *Stop*, and *Close* buttons.
2. Turn the knob to increase or decrease the amount of oxygen by the amount shown on the button. The allowable range is +1% to +100% oxygen.
3. Touch *Extend* to extend the two-minute interval. Touching *Extend* restarts the two-minute countdown timer.
4. Touch *Stop* to stop additional oxygen from being delivered and dismiss the countdown timer.

The Elevate O_2 function follows these rules:

- If the current O_2 setting is 80% or above and the selected delivery increment is > 20%, the ventilator will deliver 100% O_2 for two (2) minutes, after which the oxygen sensor will be calibrated as long as the full two-minute interval elapses without a change in O_2 delivery.
- If apnea ventilation occurs during the two-minute interval, the apnea % O_2 delivery also increases by the configured amount.
- During LOSS OF AIR SUPPLY or LOSS OF O_2 SUPPLY alarm conditions, the Elevate O_2 function is canceled if in progress, and is temporarily disabled until the alarm condition no longer exists.
- During Safety PCV, the Elevate O_2 control has no effect. During circuit disconnect and stand-by states (when the ventilator is turned on but not ventilating) the Elevate O_2 function affects the currently delivered oxygen concentration, not the set oxygen concentration.

Alarm Volume

WARNING:
The audio alarm volume level is adjustable. The operator should set the volume at a level that allows the operator to distinguish the audio alarm above background noise levels.

To institutionally configure the alarm volume

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.
2. Touch *Alarm Volume Defaults*. A screen appears allowing configuration of the alarm volume by circuit type.
3. Slide the alarm slider for each circuit type (adult, pediatric, or neonatal) or turn the knob to configure the alarm volume. The volume settings range from 1 (minimum) to 10 (maximum).
4. If done configuring the alarm volume, exit Service Mode.

To adjust alarm volume

1. Set the alarm volume by pressing the alarm volume key, then sliding the alarm volume slider or turning the knob.The alarm values range from 1 (minimum) to 10 (maximum).

Note:
A sample alarm tone sounds for verification at each volume level change. If necessary, re-adjust the alarm volume by moving the alarm volume slider to increase or decrease the volume.

Note:
The alarm volume reverts to the institutionally configured default alarm volume or factory default if the ventilator's power is cycled.

2. Dismiss the slider by touching anywhere on the GUI screen or allow to time out in five (5) seconds.

Vital Patient Data

Patient data are displayed in the Vital Patient Data banner. The operator can configure the banner for displaying the desired patient data. Reference *Areas of the GUI*, p. 4-3. A total of 14 values may be configured at one time, with eight (8) values visible, and six (6) more visible by scrolling the values using the left- and right- pointing arrows in the patient data area.

Two pages of additional patient data may be viewed by touching or swiping down on the patient data tab at the top of the GUI. Choose the respective buttons to view page one or page two. Additional patient data values may not be changed.

Reference *Patient Data Range and Resolution*, p. 11-19 for default patient data values.

To institutionally configure patient data displayed on the GUI

1. Enter Service mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.

2. Touch *Patient Data Defaults*. Five (5) layout preset buttons appear along with a list of parameters and descriptions.

3. Touch a preset button and individually select a parameter from the scrollable list below to appear in that preset's vital patient data banner. Use the right- and left-pointing arrows to configure default values for all available parameters.Additionally, touch the padlock icon above each patient data parameter on the data banner to allow (unlocked) or restrict (locked) operator configurablity of that parameter during normal ventilation.

4. When done configuring the selected preset, touch *Accept* and select another preset to configure, if desired.

5. Touch *Defaults* to return configuration to factory settings.

6. If done configuring parameters, exit Service Mode by touching *Exit*.

To configure the patient data displayed on the GUI

1. Double-tap a patient data parameter at the top of the GUI screen. A menu of buttons appears identified with patient data parameters.The parameter at the location touched will be replaced with the new parameter of choice. To view more parameters, touch the left- or right- pointing arrows to reveal more parameters.

2. Touch the button corresponding to the replacement parameter. The existing parameter is replaced with the new parameter.

3. Repeat steps 1 and 2 for as many parameters as desired.

Displaying Patient Data With a Larger Font

To improve visibility of patient data, a screen is available that appears with a larger font. Up to 14 data values may be displayed which include:

- Institutional default patient data values (if configured)
- Remaining user selected patient data values (up to 14, including waveforms and loops)

To institutionally configure the large font patient data defaults

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.

2. Touch *Large Font Patient Data Defaults*. Five layout presets appear along with a list of parameters and descriptions.

3. Touch a preset button and individually select a parameter for each of the desired patient data values.

4. Choose the desired scalar and loop waveforms for the large font patient data display. Waveform thumbnails appear in the three right-most cells of the large font data panel.

5. Touch any of the padlock icons along the right-most edge of the selected layout to prevent operator configurability of the selected row.

6. Touch *Accept* or *Accept ALL* when finished.

7. If factory defaults are desired for a preset, touch *Defaults*.

8. If done configuring parameters, exit Service Mode by touching *Exit*.

To display the large font patient data panel

1. Swipe the vital patient data banner tab downward or touch the vital patient data tab. The additional patient data panel appears.

2. Swipe the additional patient data banner's tab downward or touch the additional patient data banner's tab. Patient data appear in a larger font.

3. Swipe the large font patient data panel tab upward or touch the tab to return to the banner to its normal font size.

The large font patient data parameters are configured in the same way as described in the patient data configuration section above.

Waveforms

Green waveforms denote a mandatory inspiration, yellow waveforms denote exhalation, and orange waveforms denote a spontaneous inspiration.

The GUI can be configured to display up to three waveforms and two loops simultaneously in the waveform area. Reference *Areas of the GUI*, p. 4-3. The allowable waveforms include flow vs. time, pressure vs. time, volume vs. time, and P_{SYNC} vs. time (if IE Sync is installed and in IE Sync Monitoring). *Reference Appendix C* for more information on IE Sync. Allowable loops include pressure vs. volume and flow vs. volume. The waveforms display 60 seconds of information and can be shown in a redrawing format, or paused with the ability to enable a cursor to trace the waveform by turning the knob.

To institutionally configure waveforms and loops

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.

2. Touch *Graph Defaults*. Five (5) layout presets appear along with a list of parameters and descriptions.

3. Touch a layout preset button. The parameter(s) button outline glows, signifying that it can be changed. If more than one parameter can be changed, touch that parameter to make its outline glow.

4. Select the parameter from the list whose waveform is desired to appear on the waveforms screen.
5. Configure each of the graphic display layouts as described above.
6. Touch the padlock icon above each graphic layout to prevent operator configuration of the selected layout.
7. If factory defaults are desired for a preset, touch *Defaults*.
8. If done configuring parameters, exit Service Mode by touching *Exit*.

To configure waveforms and loops



1. Touch *Waveform Layout*, located below the displayed waveforms or the vent setup screen. The icon glows and a menu of various waveform layouts appears.
2. Touch the desired waveform(s) icon to display. The selected waveform(s) appear on the GUI screen and the dialog closes.

To change the axis scaling

1. Touch the desired waveform axis.
2. Turn the knob to change the value. For each axis, turn the knob to the right to decrease the values, and turn to the left to increase the values.

To pause waveforms



1. Touch the pause icon, located below the waveforms area. The icon glows yellow and allows the breath to complete. A cursor appears and travels along the waveform while turning the knob, displaying the x- and y-axis values.
2. Touch the pause icon again to re-activate the waveform.

Reference *To capture GUI screens*, p. 5-2 for information on storing waveforms.



Opacity

To institutionally configure screen opacity

1. Enter Service Mode, and confirm no patient is attached by touching *Configuration*. Reference *Service Mode*, p. 3-33 for instructions on entering Service Mode.
2. Touch the *Opacity* icon.
3. Turn the knob to increase or decrease the opacity.

4. Touch the padlock icon at the right side of the screen to allow or prevent operator adjustment of the screen opacity.

5. Touch *Accept* to close the dialog.

To adjust the screen opacity

1. Touch the opacity control icon. The icon glows when the opacity can be changed.



2. Turn the knob to increase or decrease the opacity.



Note:
The opacity icon can be found on the vent setup screen and on any of the respiratory mechanics maneuvers screens.

3.9 Installation Testing

Fully charge the batteries before placing the ventilator into clinical use. Reference *Battery Charging*, p. 3-4 for information on battery charging. Reference *p. 3-19* for the meaning of battery charge status LEDs and Reference *p. 3-20* for the location of battery test switch and status LEDs.

Prior to connecting a patient to the ventilator for the first time, a qualified service technician must have calibrated the ventilator's exhalation valve, flow sensors, and atmospheric pressure transducer and performed and successfully passed EST. Reference the Puritan Bennett™ 980 Ventilator *Service Manual* for instructions.

In addition, the clinician must also perform SST.

3.9.1 SST (Short Self Test)



WARNING:
Always disconnect the patient from the ventilator prior to running SST or EST. If SST or EST is performed while a patient is connected, patient injury may occur.



WARNING:
Check for circuit occlusion and/or run SST if increased pressures are observed during ventilation.

WARNING:
When changing any accessories in the patient circuit or changing the patient circuit itself, run SST to check for leaks and to ensure the correct circuit compliance and resistance values are used in ventilator calculations.

When a patient is not attached to the ventilator, run SST to check the patient circuit for:

- Gas leaks
- Circuit compliance and resistance calculations

SST is a five-minute test and must be run under any of the following conditions:

- Prior to ventilating a new patient
- When replacing the patient circuit and expiratory filter
- When connecting a different patient circuit to the ventilator
- When changing the patient circuit type
- When installing a new or sterilized expiratory filter
- When changing the humidification device type
- When adding or removing accessories to the breathing system such as a humidifier or water trap

No external test equipment is required, and SST requires minimal operator participation.

Humidification type and volume can be adjusted after running SST, however the ventilator makes assumptions when calculating resistance and compliance if these changes are made without re-running SST. For optimal breath delivery, run SST after changing humidification type and humidifier volume.

SST results are recorded in the SST results log, viewable in Service mode and in Normal mode using the configuration (wrench) icon.

Required Equipment

- Proposed patient circuit for patient ventilation
- Accessories (water traps, etc.)
- Expiratory filter and condensate vial

- Humidifier, if applicable

Other necessary items include:

- A no. 1 stopper to block the patient airway at the patient wye
- Two gas sources (air and oxygen) connected to the ventilator) at a pressure between 35 psi and 87 psi (241.3 kPa and 599.8 kPa

SST Test Sequence

To run SST

1. Ensure a patient is **NOT** connected to the ventilator.
2. So that the ventilator does not detect a patient connection, ensure that the breathing circuit wye is not attached to a test lung or covered in any way that would cause an increase in pressure at the wye.
3. Turn the ventilator on using the power switch located at the front of the BDU, below the status display. The ventilator runs POST when the power switch is turned on. Ensure the ventilator is operating on full AC power. Otherwise, SST test failures may result.
4. Wait at least 15 minutes to allow the ventilator to warm up and stabilize to ensure accurate results.



5. At the ventilator startup screen, touch *SST* or the *Configure* icon (wrench) displayed in the lower right area of the GUI. The SST history log appears along with *Patient Setup*, *Run Leak Test*, and *Run All SST* buttons.
6. Connect the patient circuit, filters, condensate vial, and all accessories to be used in patient ventilation. Ensure the patient wye is not blocked.
7. Touch *Run All SST* to perform all SST tests or t*ouch Run Leak Test* to perform the SST Leak test of the ventilator breathing circuit.
8. Touch *Accept* to continue or *Cancel* to go back to the previous screen.
9. After accepting, touch the Circuit Type button corresponding to the patient circuit type used to perform SST and to ventilate the patient (adult, pediatric, or neonatal.
10. Touch the Humidification Type button corresponding to the humidification type used for patient ventilation. If no humidifier is used, touch *HME*. If a humidifier is used, touch *Humidification Volume* and turn the knob to enter the volume. Reference *Humidifier Volumes*, p. 3-50 to determine the correct volume to enter.

11. Touch *Accept* to start SST.

12. Follow the prompts. Certain SST tests require operator intervention, and will pause indefinitely for a response. Reference *Individual SST Results*, p. 3-51 for a summary of the SST test sequence and results.

13. After each test, the ventilator displays the results. If a particular test fails, the test result appears on the screen and a choice to repeat the test or perform the next test is given. When all of the SST tests are complete, the SST status screen displays the individual test results.

14. To proceed to patient set up, (if SST did not detect an ALERT or FAILURE) touch EXIT SST, then touch *Accept* or cycle the ventilator's power.

The following table lists the tests performed during SST.

Table 3-3. SST Test Sequence

Test step	Function
SST Flow Sensor Cross Check Test	Tests O_2 and Air Flow Sensors
SST Exhalation Valve Performance	Calibrates the exhalation valve and creates a table for use during calculations
SST Circuit Pressure Test	Exercises delivery PSOL. Checks inspiratory and expiratory autozero solenoids. Cross-checks inspiratory and expiratory pressure transducers at various pressures.
SST Leak Test	Tests ventilator breathing system for leaks
SST Exhalation Filter Test	Checks for exhalation filter occlusion and exhalation compartment occlusion.
SST circuit Resistance Test	Checks for inspiratory and expiratory limb occlusions, and calculates and stores the inspiratory and expiratory limb resistance parameters.
SST circuit Compliance Test	Calculates the attached patient circuit compliance.
SST Prox (if Proximal Flow Option is installed)	Verifies functionality of Proximal Flow Subsystem

Note:
The humidifier volume setting entered during SST should always be equal to the chamber's or column's **empty** compressible volume. Please do not enter either the container's compressible volume when full or the container's water volume when full.

For humidifier containers not listed, please enter the manufacturer's published compressible volume-empty (column A) value during SST.

Table 3-4. Humidifier Volumes

Manufacturer	Model	Description	(A) Published Compressible Volume-Empty (mL)	Humidifier Volume Setting for SST (mL)
Fisher & Paykel	MR225	Infant/Ped, disposable, Manual Feed	300	300
Fisher & Paykel	MR290	Neo/Adult Disposable, Autofeed	380	380
Fisher & Paykel	MR250	Adult, Disposable, Manual Feed	480	480
Fisher & Paykel	MR210	Adult, Disposable, Manual Feed	480	480
Fisher & Paykel	MR370	Adult, Reusable, Manual Feed	725	725
Fisher & Paykel	MR340E	Infant, Reusable, Manual Feed	310	310
Teleflex (Concha)	382-60	Standard compliance	296	296
Teleflex (Concha)	382-30	Low compliance	300	300
Teleflex (Concha)	385-40	Minimal compliance	164	164

SST Results

SST reports results for each individual test.Three status indicators identify the SST results and actions to take for each.

- **Pass —** The individual SST test has met its requirements.
- **Alert —** Alerts occur when the ventilator detects one or more non-critical faults.
- **Fail —** The individual SST test did not meet its requirements.

Table 3-5. Individual SST Results

Test status	Meaning	Response
PASS	Individual SST test passed	No need to do anything, unless prompted by the ventilator.
ALERT	The test result is not ideal, but is not critical. If SST is in progress, it halts further testing and prompts for decision.	When the system prompts, touch one of these buttons: • *Repeat Test* • *Next Test* • *Exit SST*
FAIL 	The ventilator has detected a critical problem and SST cannot complete until the ventilator passes the failed test.	Eliminate leaks in the ventilator breathing system and re-run SST. Otherwise, service the ventilator and re-run SST.

SST Outcomes

WARNING:
Choose to override the ALERT status and authorize ventilation only when absolutely certain this cannot create a patient hazard or add to risks arising from other hazards.

When SST completes all of the tests, analyze the results.

Table 3-6. Overall SST Outcomes

Final Outcome	Meaning	Response
PASS	All SST tests passed.	Touch *Patient Setup* to set up the patient for ventilation:
ALERT	The ventilator detected one or more faults. Choose to override the ALERT status and authorize ventilation only when absolutely certain this cannot create a patient hazard or add to risks arising from other hazards.	To override the alert, touch *Override SST*, then touch *Accept*. To exit SST, touch *Exit SST*.
FAIL	One or more critical faults were detected. The ventilator enters the SVO state and cannot be used for normal ventilation until SST passes.	Check the patient circuit to determine the problem or restart SST with a different patient circuit. Touch *Repeat Test*, *Run All SST*, or *Exit SST*, then touch *Accept*.

If touching *Override SST,* observe the following warning:

A single circuit leak test can be run, but the full suite of SST test must successfully pass before releasing the ventilator for clinical use.

If a complete SST is interrupted and ventilation was allowed before starting SST, normal ventilation is allowed if

- SST did not detect any failures or alerts before the interruption, and
- no other errors that would prevent ventilation occurred, and
- there were no changes to the circuit type at the start of the interrupted SST.

During SST, the ventilator displays the current SST status, including the test currently in progress, results of completed tests. Test data are available in Service Mode where applicable or are displayed on the screen. The ventilator logs SST results, and that information is available following a power failure. The alarm silence and alarm reset keys are disabled during SST, as well as the *Manual Inspiration*, *Inspiratory Pause*, and *Expiratory Pause* keys.

3.9.2 EST (Extended Self Test)

The ventilator's Extended Self Test (EST) function is designed to verify the ventilator's operational subsystem integrity.

All required software support to perform EST is resident on the ventilator. EST requires approximately ten (10) minutes to complete.

Note:
SST is not part of the EST test suite. To determine patient circuit resistance and compliance, run SST.

EST Self Test Prerequisites

Follow all identified guidelines when performing the EST self test. Inspect all equipment required for any self test to ensure it is not damaged in any way.

1. Collect all required equipment prior to performing any self test of the ventilator. Successful self test is not possible without the use of the listed equipment.
2. Disconnect the ventilator from the patient.
3. Fully charge the primary ventilator battery.

4. Connect the ventilator to AC power using the hospital-grade power cord until completion of any self test.
5. Ensure the ventilator is powered down.
6. Ensure both air and oxygen sources register pressure between 35 and 87 psi (241 to 599 kPa).

To perform Extended Self Test (EST) or to access additional service functions, the ventilator must be in Service Mode. Reference *Service Mode*, p. 3-33.

Note:

15. While in the Service Mode, normal ventilation is not allowed.

WARNING:
Always disconnect the ventilator from the patient before running EST. Running EST while the ventilator is connected to the patient can injure the patient.

WARNING:
A fault identified during this test indicates the ventilator or an associated component is defective. Rectify the fault and perform any required repairs prior to releasing the ventilator for patient use, unless it can be determined with certainty that the defect cannot create a hazard for the patient, or add to the risks which may arise from other hazards.

Perform EST during any of the listed conditions.

- Prior to initial installation and first time usage of the ventilator
- Every six months
- Before any preventive maintenance
- Following ventilator service or repair
- As part of the ventilator's routine performance verification

During EST, the ventilator displays the current EST status, including the test currently in progress, results of completed tests, and measured data (where applicable). The ventilator logs EST results, and that information is available following a power failure. The ventilator disables several offscreen keys located on the bezel of the GUI during EST.

- Alarm silence

- Alarm reset
- Manual inspiration
- Inspiratory pause
- Expiratory pause

Run tests either as a group or as single tests for troubleshooting purposes.

Equipment for EST

- Covidien gold standard test circuit
- Number one stopper
- Air and oxygen sources, both at 35 to 87 psi (241 to 599 kPa).
- An adult-sized expiratory filter

Note:
Attempts to run EST with a Neonatal filter can cause some EST tests to fail.

Note:
If using Air Liquide™*, Dräger™*, and SIS air/oxygen hose assemblies, certain EST tests may fail when using supply pressures less than50 psi (345 kPa) based on excessive hose restriction.

3.9.3 EST Test Sequence

Note:
If the ventilator has not reached normal operating temperature from recent usage, allow it to warm up for at least 15 minutes in Service Mode prior to running EST to ensure accurate testing.

To perform EST

1. Review and perform all self test prerequisites. Reference *EST Self Test Prerequisites*, p. 3-52.
2. Collect the appropriate equipment. Reference *Equipment for EST*, p. 3-54.
3. Access Service Mode. Reference *Service Mode*, p. 3-33.

4. Verify all three CALIBRATION tests under the CALIBRATION tab have passed.
5. Touch the SELF TEST tab from the horizontal banner at the top of the monitoring screen.
6. Touch the EST tab from the left-hand menu options.
7. Touch *Run All* to run all tests in sequence or select the desired individual test.
8. Choose one of the available options: touch *Accept* to continue; touch *Cancel* to go back to the previous screen; or touch *Stop* to cancel EST.
9. Follow the prompt to remove the inspiratory filter and connect the gold standard circuit.
10. Touch *Accept*.
11. Follow prompts to complete EST. The EST tests require operator intervention, and will pause indefinitely for a response. Reference *EST Test Sequence*, p. 3-54.
12. At the DISCONNECT O_2 prompt, disconnect the high pressure oxygen source.
13. At the CONNECT AIR AND O_2 prompt, connect both high pressure air and oxygen sources.
14. Touch *Run All* or select the desired individual test. After each test, the ventilator displays the results.
15. If a particular test fails, either repeat the test or perform the next test.
16. When all of the EST tests complete, review test results by pressing each individual test listed on the left side of the GUI.
17. Touch EXIT EST.
18. Touch ACCEPT. The ventilator reruns POST and then displays the ventilator startup screen.

Table 3-7. EST Test Sequence

EST Test Step	Function	Required User Interaction
Zero Offset	Tests inspiratory and expiratory pressure transducers and flow sensors at ambient pressure.	Follow prompts

Table 3-7. EST Test Sequence (Continued)

EST Test Step	Function	Required User Interaction
Leak Test	Determines ability of system to hold pressure.	Follow prompts
Mix Leak	Verifies integrity of the mix system.	Follow prompts
Mix PSOL	Verifies mix PSOL function.	None
Mix Accumulator	Verifies mix accumulator pressure sensor and over-pressure switch function.	None
Circuit Pressure	• Checks inspiratory and expiratory autozero solenoids • Cross-checks safety valve, inspiratory and expiratory pressure transducers at various pressures • Verify the autozero solenoid's function	None
Flow Sensor Cross Check Test	Verifies all flow sensors and PSOLs at specified flow volumes.	None
Delivery PSOL	Verifies delivery PSOL current function.	None
Exhalation Valve (EV) Loopback	Verifies exhalation valve.current and loopback current are within range.	None
Exhalation Valve (EV) Pressure Accuracy	Verifies current versus pressure values in flash memory correspond with actual installed exhalation valve.	None
Exhalation Valve (EV) Performance	Verifies the exhalation valve operates within specifications of the last exhalation valve calibration.	None
Exhalation Valve (EV) Velocity Transducer	Verifies the velocity transducer is sending a signal and the control circuit recognizes it. It does not verify the quality of the signal.	None
Safety System	Tests safety valve operation.	None
Backup Ventilation	Verifies backup ventilation systems: mix, inspiratory, and exhalation.	None
Communication	Verifies GUI communication ports function, both serial and ethernet.	None
Internal Storage	Verifies internal storage device function.	None
LCD Backlight	Verifies GUI LCD backlight intensity function.	None

Table 3-7. EST Test Sequence (Continued)

EST Test Step	Function	Required User Interaction
Status Display	**Verifies status display function** • Verifies LCD function • Communicates with BD CPU	None
GUI Audio	Tests GUI alarm indicators, cycling through each alarm status indication.	Follow prompts
BD Audio	Verifies BD audible alarm is functional. Also verifies power fail capacitor can operate loss-of-power alarm.	Follow prompts
Rotary Knob Test	Verifies knob rotation function.	Follow prompts
Offscreen Key Test	Verifies GUI bezel key function.	Follow prompts
Ventilator Battery	Tests ventilator battery and power distribution.	Follow prompts

3.9.4 EST Test Results

Table 3-8. Individual EST Results

Test Status	Meaning	Response
PASS	Individual EST test passed	No need to do anything unless prompted by the ventilator
ALERT 	The test result is not ideal, but is not critical. If EST is in progress, it halts further testing and prompts for decision.	When the system prompts, select: REPEAT TEST, NEXT TEST, or STOP, then touch ACCEPT.
FAIL 	EST not successfully passed.	Select: REPEAT TEST, NEXT TEST, or STOP, then touch ACCEPT.
NEVER RUN	Test still requires successful PASS.	Run all EST tests.

When EST completes all of the tests, analyze the results.

Table 3-9. Overall EST Outcomes

Final Outcome	Meaning	Response
PASS	All EST tests passed	EST successfully completed. Select other SERVICE MODE functions or prepare for SST tests prior to returning the ventilator for patient usage.
ALERT 	The ventilator detected one or more faults. The test result is not ideal, but is not critical.	When the system prompts, select: REPEAT TEST, NEXT TEST, or STOP, then touch ACCEPT.
FAIL 	One or more critical faults were detected. The ventilatorenters the SVO state and cannot be used for normal ventilation until SST passes. Service is required.	When the system prompts, select: REPEAT TEST, NEXT TEST, or STOP, then touch ACCEPT.
OVERRIDDEN	ALERT status overridden by user.	Select next desired test.

Touching *Override Est* results in the following warning:

WARNING:
Choose to override the ALERT status and authorize ventilation only when absolutely certain this cannot create a patient hazard or add to risks arising from other hazards.

3.10 Operation Verification

Before ventilating a patient, **you must perform SST and alarms tests with passing results**. Reference *To run SST*, p. 3-48 and Reference *Alarm Testing*, p. 6-9 as well.

4 Operation

4.1 Overview

This chapter describes Puritan Bennett™ 980 Series Ventilator operation and includes the following sections:

- Setting up the ventilator
- How to use the ventilator
- How to use the ventilator's graphical user interface (GUI)
- How to set or change main, alarm, or apnea settings
- How to test alarms
- How to calibrate, enable, or disable the O_2 sensor
- How to perform inspiratory and expiratory pause maneuvers.
- How to use non-invasive ventilation (NIV)

4.2 Ventilator Function

Air and oxygen from wall sources or cylinders enter the ventilator and flow through individual oxygen and air flow sensors. The gases are then mixed in the mix module's accumulator. A pressure-relief valve in the mix module's accumulator prevents over-pressurization. The mix module also contains an oxygen sensor which monitors the air-oxygen mixture according to the operator-set O_2% setting.

After the gas mixes, it flows to the inspiratory pneumatic system, where the breath delivery flow sensor measures the gas flow and controls a PSOL valve for proper breath delivery tidal volumes and pressures. The inspiratory pneumatic system contains a safety valve to avoid over-pressure conditions before flowing through bacteria filters to the patient through the inspiratory limb of the patient circuit. Upon exhalation, gas flows out the patient circuit expiratory limb, through the expiratory bacteria filter, through the exhalation valve,

which includes the exhalation valve flow sensor, and through the exhalation port.

4.3 Ventilator Setup

WARNING:
To avoid interrupted ventilator operation or possible damage to the ventilator, always use the ventilator on a level surface in its proper orientation.

To set up the ventilator

1. Connect the ventilator to the electrical and gas supplies. Reference *Power Cord Retainer on BDU*, p. 3-7 and Reference *Connecting the Ventilator to the Gas Supplies*, p. 3-9.
2. Connect the patient circuit to the ventilator. Reference the figures on *p. 3-16* and *p. 3-17* to connect the adult/pediatric or neonatal patient circuits, respectively.
3. Turn the ventilator ON using the power switch. Reference *Ventilator Power Switch and AC Indicator*, p. 2-26.
4. Before ventilating a patient, run SST to calculate the compliance and resistance with all items included in the patient circuit. Reference *To run SST*, p. 3-48.

4.4 User Interface Management

The user interface is structured with a GUI and a status display. The GUI provides access to ventilator controls and patient data. The status display is a small LCD panel which acts as a back up to the GUI in the event of a GUI failure. Reference *Status Display*, p. 2-28 for more information about the status display.

The status display is not interactive.

During normal ventilator operation, the following information appears on the status display:

Current power state (AC or DC)

- Batteries installed / charge status
- Visual indication of audible alarm volume
- Circuit pressure graph displaying P_{PEAK}, PEEP, and pressure-related alarm settings

Reference *Status Display*, p. 2-28 for information about displayed items during Service mode.

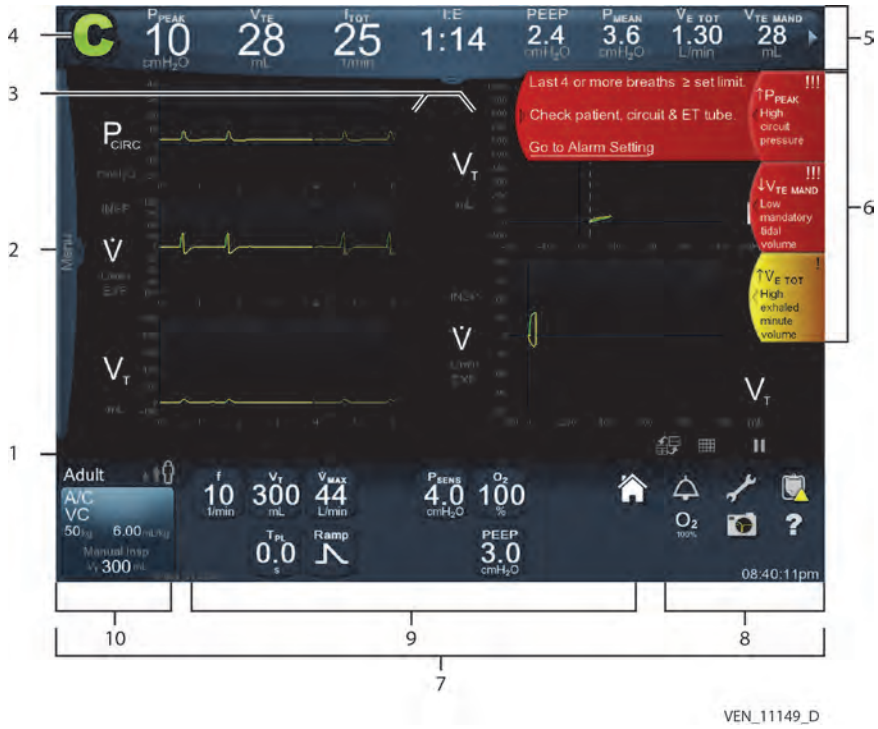
Using the GUI

The GUI is used to interact with the ventilator while it is ventilating a patient or in any of its operating modes.

Caution:
Do not lean on the GUI or use it to move the ventilator. Doing so could break the GUI, its locking mechanism, or tip the ventilator over.

The GUI is divided into several areas.

Figure 4-1. Areas of the GUI



1. **Prompt area —** Located beneath the waveforms. Any prompts or messages display here. Examples include soft and hard bound messages, PAV+ and IE Sync startup messages, Oxygen sensor calibration in progress and various other informational messages.

Note:
A ***soft bound*** is a selected value that exceeds its recommended limit and requires acknowledgment to continue. Hard bounds have minimum and maximum limits

beyond which values cannot be selected, however if the desired value is equal to a settings ***hard bound***, then it is allowable.

2. **Menu tab —** Located on the left side of the GUI screen. Swiping the tab to the right and touching *Setup* causes the Vent, Apnea, Alarm, and More Settings tabs to appear. Touching those tabs opens screens so that changes to ventilator settings, apnea settings and alarm settings can be made.

3. **Waveform area —** Located in the center of the GUI screen. Shows various breath waveforms. Reference *To configure waveforms and loops*, p. 3-45 for information on how to configure graphics.

4. **Breath Phase Indicator —** During normal ventilation, the GUI displays a breath indicator in the upper left corner which shows the type of breath [Assist (A), Control (C), or Spontaneous (S)] currently being delivered to the patient, and whether it is in the inspiratory or expiratory phase. The breath indicator is updated at the beginning of every inspiration, and persists until the next breath type update. During inspiration, assist (A) and control (C) breath indicators glow green and spontaneous (S) breath indicators glow orange, each appearing in inverse video where the indicator appears black surrounded by the colored glow. Reference *Areas of the GUI*, p. 4-3. During the expiratory phase the breath indicators appear as solid colors (green during assist or control breaths and orange during spontaneous breaths).

5. **Vital Patient data banner —** Located across the top of the GUI screen. The patient data banner displays monitored patient data and can be configured to show desired patient data. Reference *Vital Patient Data*, p. 3-42 for information on configuring patient data for display.

6. **Alarm banners —** Located on the right side of the GUI screen. Indicates to the operator which alarms are active, and shown in a color corresponding to priority (high is red and flashing, medium is yellow and flashing, low is yellow and steady).

7. **Constant access icons —** Located at the lower right of the GUI screen. This area allows access to home (house), configure (wrench), logs (clipboard), elevate oxygen percentage (O_2), and help (question mark) icon. These icons are always visible regardless of the function selected on the GUI.

8. **Constant access area —** Consists of the Current Settings area and the Constant access icons. This area allows access to any of the patient setup variables shown in these areas. Touching an icon causes the particular menu for that variable to appear.

9. **Current settings area —** Located at the lower center of the GUI screen. The ventilator's current active settings display here. Touching any of the current settings buttons causes a dialog to appear, allowing changes using the knob.

10. **Vent Setup Button —** Located at the lower left of the GUI screen. Touching this button allows access to the ventilator setup screen.

Adjusting GUI Viewing Properties

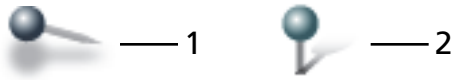
Screen Opacity

The opacity control enables the operator to adjust the opacity of the displayed information between 50% and 100%. At 50%, the displayed image is semi-transparent, and at 100%, the displayed image is opaque. The opacity value remains as set if power is cycled and if the same patient is ventilated. If a new patient is ventilated, the opacity defaults to 85%. Reference *To adjust the screen opacity*, p. 3-46 for instructions on adjusting this feature.

Pushpin Feature

The pushpin feature prevents a dialog from closing under certain conditions when it is pinned. Like the opacity control, the pushpin appears on the settings screen after a new patient starts ventilation.

Figure 4-2. Pushpin Icon



1 Pushpin icon – unpinned state

2 Pushpin icon – pinned state

To use the pushpin

1. When a dialog is open, for example, if *Accept* or *Accept ALL* buttons are available, touch the unpinned pushpin icon to pin the dialog and hold it open.
2. Touch *Close* to close the dialog.

Display Brightness

Display brightness can be controlled manually.This feature is institutionally configurable. Reference *Screen Brightness and Keyboard Backlight (Light Settings)*, p. 3-39. The brightness range is from 1% to 100% with 1% resolution. The default value is 80%.

To manually adjust display brightness

1. Press the display brightness key.
2. Slide the brightness slider to the right to increase the brightness level or to the left to decrease the brightness level. Alternatively, turn the knob to increase or decrease the brightness level. The control disappears from the screen in approximately five (5)seconds.

Display Lock

The primary display provides a display lock key to prevent inadvertent changes to settings. When active, the display lock disables the touch screen, knob, and off-screen keys (other than the display lock key) and illuminates an LED on the display bezel. An image of the display lock icon appears transparently over anything displayed on the GUI, should the operator attempt to use the GUI. Any new alarm condition disables the display lock and enables normal use of the GUI.

To lock and unlock the display



1. Press the display lock key on the GUI. The keyboard LED illuminates and a transparent locked icon appears on the screen, indicating display lock. The icon shortly disappears, but if the operator tries to activate any of the touch screen controls, the icon re-appears.

2. To unlock the display, press the display lock key again. The display lock LED turns off and an unlocked image briefly appears on the screen.

Using Gestures When Operating the GUI

The GUI incorporates a gesture-based interface where features can be actuated with the fingers using different motions. The following table explains gestures used with the GUI.

Table 4-1. Gestures and Their Meanings

Gesture	Description	Used for	How to Use
Swipe	Quickly brush the screen surface with the fingertip.	Opening or closing dialogs or panels that slide in and out from the screen sides or top, moving waveform data, expanding or collapsing tooltips, scrolling lists, or alarm banners, maximizing or minimizing waveforms.	Swipe toward the center of the screen to open dialogs or panels. Swipe toward the side of the screen (or upward if viewing the additional patient data or large font patient data panels) to close. To move a paused waveform, swipe in the desired direction. Swipe upward anywhere on a waveform to maximize it, and swipe downward on the maximized waveform to minimize it. Swipe a tooltip upward to expand to a long description and downward to collapse to a short description. A downward swipe anywhere in the patient data area opens the additional patient data panel, and another swipe on the additional patient data tab displays the large font patient data panel.

Table 4-1. Gestures and Their Meanings (Continued)

Gesture	Description	Used for	How to Use
Double-tap	Rapidly touch the screen surface twice with one finger.	Maximizing or minimizing the viewable area of a dialog, control, or waveform, expanding or collapsing tooltips	Double-tapping maximizes the viewable waveform area or shows the long description of a tooltip. Double-tapping again minimizes the viewable waveform area or shows the short description of a tooltip. If the control is configurable, double tapping produces the configuration pop-up menu.
Drag	Move the fingertip over the screen surface without losing contact.	Changing x- and y- axis scales, moving the waveform cursor, moving scrollbars, scrolling lists. Scrolling speed varies depending upon how far outside the list boundary the finger is positioned.	Touch the axis and drag to the right to increase the waveform x-axis scale, and to the left to decrease. Touch the axis and drag upward to increase the y-axis scale and downward to decrease. To move the cursor (when the waveform is paused), touch the cursor and drag it right or left. The graph responds similarly. Scroll a list by dragging the scrollbar right or left or up or down. The list scrolls according to the direction of the finger movement. An automatic scrolling feature starts if the finger is dragged from the inside of a list to outside its boundary. The farther outside the boundary the finger is dragged, the faster the list scrolls.
Touch and hold	Touch an item and hold for at least 0.5 seconds.	Displaying a tooltip dialog on whatever item is touched. The tooltip appears to glow indicating the touch and hold action.	N/A
Drag and drop	Touch and drag an item to another location and lift finger to drop.	Dragging help icon to describe an onscreen item.	Drag the help icon, located at the lower right of the GUI screen, to the item in question and drop. If a blue glow appears, a tooltip is available and appears with information about that item (for example, a control or symbol).

4.5 Ventilator Operation

Caution:
Do not set containers filled with liquids on the ventilator, as spilling may occur.

After turning on the ventilator, it will display a Covidien "splash screen," and run Power On Self Test (POST). After the splash screen appears, the ventilator gives a choice to ventilate the same patient or a new patient, or run SST.

Ventilation parameters are entered via the graphical user interface (GUI) using the following general steps:

1. Touch the setting displayed on the GUI.
2. Turn the knob to the right to increase or to the left to decrease the value.
3. Touch *Accept* to apply the setting or *Accept ALL* to apply several settings at once.

Note:
Quick Start allows for rapid setup and initiation of mechanical ventilation. Review Quick Start parameters and ensure they are consistent with institutional practice before using this feature.

WARNING:
Prior to patient ventilation, select the proper tube type and tube ID.

To use Quick Start

1. Touch *New Patient*.
2. Touch the highlighted *PBW* button or *Gender/Height*.
3. Turn the knob to adjust the patient's PBW or gender and height (if gender is selected, the height selection becomes available).
4. Touch *Quick Start*.
5. Connect the circuit wye adapter to the patient's airway or interface connection. The patient is ventilated with the institutionally configured or factory configured *QUICK START* defaults according to the PBW or gender/height entered, and circuit type used during SST. There is no prompt to review the settings and the waveforms display appears.

Note:
Connecting the circuit wye adapter to the patient's airway or interface connection prior to making the ventilation settings causes the ventilator to begin ventilation using Safety Pressure Control Ventilation (Safety PCV) and annunciate a PROCEDURE ERROR alarm. As soon as the ventilator receives confirmation of its settings (by touching *"Accept"* or *'Accept ALL"*), it transitions out of safety PCV, resets the alarm, and delivers the chosen settings. Reference *Safety PCV Settings*, p. 10-72 for a listing of

these settings.

To resume ventilating the same patient

1. Touch *Same Patient* on the GUI screen. The previous ventilator settings are displayed on the screen for review prior to applying the settings to the patient.

2. If the settings are acceptable, touch *Accept* to confirm. To change any settings, touch the setting, turn the knob clockwise to increase the value of the setting or counter-clockwise to decrease the value of the setting, and touch *Accept* to confirm. To make several settings changes at once, make the desired changes, then touch *Accept ALL* to confirm. The appearance of the settings changes from white, non-italic font showing the current setting to yellow italics (noting the pending setting). After the settings are accepted, the appearance changes back to white non-italic font.

3. Connect the circuit to the patient's airway to initiate ventilation.

To ventilate a new patient

1. Touch *New Patient* on the GUI screen. The *New Patient* settings screen appears to enter the ventilation control parameters. Reference *Ventilator Settings Range and Resolution*, p. 11-8 for default ventilator parameter settings.

Figure 4-3. New Patient Settings



2. Enter the patient's PBW or gender and height (if gender is selected, the height selection becomes available).

3. If the default ventilator settings are appropriate for the patient, touch *START* to confirm the settings, otherwise, touch a ventilator setting and turn the knob to adjust the parameter. Continue this process for all parameters needing adjustment.

4. Touch *Accept* or *Accept ALL* to confirm the change(s).

5. Connect the circuit to the patient's airway to start ventilation.

4.5.1 Ventilator Settings

WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

The following ventilator settings appear at the new patient setup screen:

- **Predicted Body Weight (PBW)** — Adjust the patient's PBW, or select the patient's gender and height. Reference *Predicted Body Weight (PBW) Calculation*, p. 4-21.

- Ventilation **type** — Determines the type of ventilation to be delivered [Invasive or Non-invasive (NIV)]

  - Invasive — Conventional ventilation using endotracheal (ET) or tracheostomy (trach) tubes

  - Non-invasive (NIV) — Ventilation using non-vented full-face masks, nasal masks, infant nasal prongs, or uncuffed ET tubes. Reference *Non-invasive Ventilation (NIV)*, p. 4-22

- **Mode —** Specify the breathing mode (A/C (assist/control), SIMV (synchronous intermittent mandatory ventilation), SPONT (spontaneous ventilation), BiLevel (if the BiLevel option is installed), or CPAP. CPAP is only available when circuit type is neonatal and vent type is NIV. Reference *Ventilator Settings Range and Resolution*, p. 11-8, Mode setting.

- **Mandatory type —** Select PC (pressure control), VC (volume control), or VC+ (volume control plus)

- **Spontaneous type —** If SIMV or BiLevel was selected as the Mode, specify PS (pressure support) or TC (tube compensation. If SPONT was selected as the Mode, specify PS (Pressure Support), TC (Tube Compensation), VS (Volume Support) or PAV+ (Proportional Assist Ventilation) (if the PAV+ software option is installed).

Note:
VS, PAV+, and TC are only available during INVASIVE ventilation.

- **Trigger type —** Select pressure- triggering (P_{-TRIG}), flow-triggering ($\dot{V}_{-TRIG}$), or IE Sync- triggering (if the IE Sync option is installed, and only in SPONT mode). *Reference Appendix C* in this manual for detailed information on the IE Sync software option. Pressure-triggering and IE Sync-triggering are not available when vent type is NIV. If ventilating a neonatal patient, only flow triggering is available.

Other ways to access the vent setup screen:



- Touch *Vent Setup* at the bottom left of the GUI display
- Swipe the menu tab on the left side of the GUI and touch *Setup*.

Figure 4-4. Open Menu Tab



1 Setup button

Figure 4-5. New Patient setup Screen



To enter settings into the ventilator

1. Select Vent type, Mode, Mandatory type, Spontaneous type and Trigger type by touching the corresponding button.
2. Touch the ventilator setting button needing changes.
3. Adjust the setting value.
4. Continue in this manner until all changes are made, then touch *Accept* or "*Accept ALL*".
5. Touch *START*. Ventilation does not begin until the breathing circuit is connected to the patient's airway. After ventilation begins, waveforms begin plotting on the displayed waveforms axes. Reference *Waveforms*, p. 3-44 for information on setting up the graphics display.

If changes to any settings are required, return to the Vent Setup screen as described above, or touch a setting icon in the current settings area. Reference *Areas of the GUI*, p. 4-3, item 9.

Note:
A yellow triangle icon appears on tabs and buttons displayed on the GUI containing unread or un-viewed items. When the item containing the icon is touched, the icon disappears.

Note:
To make any settings changes after completing patient setup, touch the Vent tab on the left side of the Setup dialog and make settings changes as described above. The current setting appears in white font and changes to yellow italics to note the new value is pending.Touch *Accept* or *Accept ALL* to confirm a single change or a batch of changes. Once the settings are accepted, their appearance changes to white font.

Note:
Selecting *QUICK START*, *Accept*, *Accept ALL* or *Start* from the Setup dialog implements all settings in **ALL** four Setup tabs (Vent Setup, Apnea, Alarms, and More Settings) and dismisses the Setup dialog.

Tube Compensation

Tube Compensation is a spontaneous breath type selected during ventilator setup. It allows the ventilator to deliver additional positive pressure to overcome the resistance imposed by the patient's artificial airway.
Reference *p. 4-12* for more information on setting up the ventilator. Reference *Ventilator Settings Range and Resolution*, p. 11-8 for details of specific tube compensation settings.

To enable TC

1. Touch the VENT tab on the GUI screen. Reference *New Patient setup Screen*, p. 4-12.
2. Touch SPONT for the mode selection.
3. Touch TC for Spontaneous type.
4. Finish setting up the ventilator as described (reference *p. 4-12* for information on entering ventilator settings.
5. Select the tube type (either endotracheal or tracheostomy) and set the tube ID to correspond to patient settings.

- After making the changes, touch *Accept* to apply the new settings, or *Cancel* to cancel all changes and dismiss the dialog.

Adjust Tube Type, Tube ID, and Humidification

WARNING:
To prevent inappropriate ventilation with TC, select the correct Tube Type (ET or Tracheostomy) and tube inner diameter (ID) for the patient's ventilatory needs. Inappropriate ventilatory support leading to over-or under-ventilation could result if an ET tube or trach tube setting larger or smaller than the actual value is entered.



To select new settings for the tube, follow these steps

1. Touch *Vent Setup* on the GUI screen to display the Ventilator setup screen.
2. Touch *Tube Type* or *Tube ID* for the value to be changed.
3. Turn the knob to change the setting.
4. Make other tube settings, as necessary.
5. Touch *Accept* or *Accept ALL* to apply the new settings, or *Cancel* to cancel all changes and dismiss the dialog.

Note:
The tube type and tube ID indicators flash if TC is a new selection, indicating the need for entry of the correct tube type and tube ID.

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To select new settings for the humidifier, follow these steps

1. From the Ventilator setup screen, touch the More Settings tab. A dialog appears containing selections for humidifier type and volume.

   A "Humidifier Volume" button appears below the selection only if "Non-Heated Expiratory Tube" or "Heated Expiratory Tube is selected as the humidifier type.
2. Turn the knob to enter a value equal to the dry volume of the humidifier chamber being used.
3. Touch *Accept* or *Accept ALL* to apply the new settings, or *Cancel* to cancel all changes and dismiss the dialog.

4.5.2 Apnea Settings

After making the necessary changes to the ventilator settings touch the Apnea tab on the left side of the Setup dialog. Although changing the apnea settings is not required, confirm the default settings are appropriate for the patient. Apnea ventilation allows pressure control or volume control breath types. Parameters in pressure-controlled apnea breaths include *f*, P_I, T_I O_2%, and T_A. Volume controlled apnea breath parameters are *f*, V_T, $\dot{V}_{MAX}$, Flow pattern, O_2%, and T_A.

Note:
If *QUICK START* is chosen, the apnea tab on the Vent Setup screen shows a yellow triangle, indicating the apnea settings have not been reviewed.

Figure 4-6. Apnea Setup Screen



To set apnea parameters

1. Select the desired apnea breath type (PC or VC).
2. Enter the desired apnea settings in the same manner as for the ventilator settings.
3. Touch *Accept* or *Accept ALL* to confirm apnea settings.

During apnea pressure ventilation, apnea rise time % is fixed at 50%, and the constant parameter during a respiratory rate change is T_I.

4.5.3 Alarm Settings

After accepting the apnea settings, the display returns once more to show the waveforms. Return to the Vent Setup dialog and touch the Alarms tab on the left side of the GUI screen or touch the alarm icon in the constant access icons area of the GUI screen. The alarms screen appears with the default alarm settings. Reference *Alarms Settings Screen*, p. 4-17. Review and adjust the alarm settings appropriately for the patient.

Note:
If Quick Start is chosen, the alarms tab on the dialog shows a yellow triangle, indicating the alarm settings have not been reviewed.

Note:
Reference *Alarm Settings Range and Resolution*, p. 11-17 for new patient default alarm values. These **defaults** cannot be changed. The clinician can adjust alarm settings by following the procedure below. The alarm settings are retained in memory when the ventilator's power is cycled and same patient is selected.Otherwise, current settings revert to new patient defaults when a new patient is selected.

Figure 4-7. Alarms Settings Screen



To adjust the alarm settings

1. Touch each alarm setting slider of the alarm(s) to change. Alarm settings are available for P_{PEAK}, f_{TOT}, $\dot{V}_{E\ TOT}$, $V_{TE\ MAND}$, $V_{TE\ SPONT}$, and V_{TI} parameters.
2. Turn the knob clockwise to increase the value, or counter-clockwise to decrease the value.
3. Continue until all desired alarms are set as necessary.
4. Touch *Accept ALL* to confirm the alarm settings.

Note:
There is an additional alarm setting for TC, PAV+, VS, and VC+ breath types: High inspired tidal volume ($\uparrow V_{TI}$). This alarm condition occurs when the inspired tidal volume is larger than the setting value. A $\uparrow V_{TI}$ alarm will also cause breath delivery to transition to the exhalation phase to avoid delivery of excessive inspiratory volumes.

WARNING:
Prior to initiating ventilation and whenever ventilator settings are changed, ensure the alarm settings are appropriate for the patient.

WARNING:
Setting any alarm limits to OFF or extreme high or low values, can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations that may require intervention.

Reference *To adjust alarm volume*, p. 3-41 to ensure alarm volume is adjusted properly.

Note:
A sample alarm tone sounds for verification at each volume level change. Re-adjust the alarm volume by moving the alarm volume slider to increase or decrease the alarm volume.

Note:
Do not block the patient wye while the ventilator is waiting for a patient connection. Otherwise the blockage could imitate a patient connection.

4.5.4 Alarm Screen During Operation

During ventilator operation, the alarm screen appears with indicators to let the operator know the current patient data value for each parameter (item 1), the parameter alarm settings (items 2 and 3), recent range of patient data values for the last 200 breaths (item 4). If an alarm occurs, the slider and corresponding limit button show a color matching the alarm's priority. Reference *Alarm Screen During Operation*, p. 4-19.

Figure 4-8. Alarm Screen During Operation



1	Pointers show current value of patient data corresponding to the alarm parameter	3	Low alarm setting (in this case $\downarrow V_{TE\ SPONT}$)
2	High alarm setting (in this case $\uparrow V_{TE\ SPONT}$)	4	Range of patient data values for the particular parameter during the last 200 breaths

4.5.5 Making Ventilator Settings Changes

If, during ventilation, settings changes are necessary that don't involve changes to PBW, Mode, Breath types, or Trigger types, the current settings area located at the lower portion of the GUI screen can be used. Reference *Areas of the GUI*, p. 4-3 for the location of the current settings area.

To change a ventilator setting using the "current settings" area

1. In the current settings area, touch the parameter whose value needs to be changed. A dialog appears containing buttons for all ventilator settings, with the selected setting highlighted.
2. Touch and turn the knob for any other settings that need to be changed.
3. Touch *Accept or Accept ALL*.

To change a setting using the Vent Setup button

1. Touch *Vent Setup*.
2. Change the settings as described previously.
3. Touch *Accept* or *Accept ALL* to confirm the changes.



The ventilator settings and the alarm settings chosen remain in memory after the a power cycle, as long as the same patient is chosen when the ventilator is set up again. If a new patient is being ventilated, the ventilator and alarm settings revert to their default values. If all power is lost (both AC and battery), the ventilator and alarm settings in effect prior to the power loss are automatically restored if the power loss duration is five (5)minutes or less. If the power loss lasts longer than five minutes, ventilation resumes in Safety PCV. Ventilator and alarm settings must be reset for the patient being ventilated. Reference *Safety PCV Settings*, p. 10-72 for a list of these settings.

To use the *Previous Setup* button

1. To return to the previous settings, touch *Previous Setup* on the GUI screen. The ventilator restores the main control and breath settings previously used, as well as the alarm and apnea settings, and prompts a review by highlighting the previous values in yellow. The ventilator, alarm, and apnea settings tab text is also shown in yellow and the tabs show a yellow triangle, indicating there are previous settings that have not been reviewed.
2. If the settings are acceptable, touch *Accept ALL*.

The *Previous Setup* button disappears when the previous settings are confirmed and re-appears when ventilating with new settings.

4.5.6 Constant Timing Variable During Respiratory Rate Changes

A breath timing graph appears at the bottom of the setup screen which illustrates the relationship between inspiratory time, expiratory time, I:E ratio,

respiratory rate, and the effects on breath timing due to flow pattern, tidal volume, and $\dot{V}_{MAX}$ during mandatory PC, VC, BiLevel, or VC+ breaths. With BiLevel, PC and VC+ breaths, three "padlock" icons are located underneath the breath timing graph allowing the operator to select, from left to right, T_I, I:E ratio, or T_E as the constant variable during rate changes (or T_H, T_H:T_L ratio, or T_L in BiLevel). If the ventilation mode is SPONT, the padlock icons do not appear, and the breath timing graph only displays T_I for a manual inspiration. If the mandatory type is VC, the icons do not appear, but the breath timing graph displays T_I, I:E ratio, and T_E.

To choose a constant timing variable for rate changes

1. Touch a padlock icon corresponding to the parameter to make constant during rate changes (this changes the padlock's appearance from unlocked to locked). The "locked" parameter glows in the settings area.
2. Turn the knob to adjust the parameter's value.
3. Touch *Accept*.

4.6 Predicted Body Weight (PBW) Calculation

Many default ventilator and alarm settings are based on patient PBW. Either through the entry of height and gender or directly via setting PBW, the PBW range spans at least 0.3 kg (0.66 lb) through at least the 155 kg (342 lb) male and the 150 kg (331 lb) female. Understanding how the ventilator operates at the very low end of the range of PBW requires awareness that an entry or prediction for PBW drives the value of a delivered volume, which has a lower limit of 2.0 mL (if using the NeoMode 2.0 option).Data for adult male and female PBW as a function of height were calculated by applying the equations presented on www.ards.net.

Assume the ventilator (via direct height or PBW entry) registered a PBW of 0.3 kg. If a delivered volume of 4 mL/kg (PBW) was specified, the required volume would equal only 1.2 mL, which is less than the ventilator minimum of 2.0 mL. At a desired 4 mL/kg, the infants' PBW would need to be at least 0.5 kg or the desired volume must be reset to greater than 4 mL/kg (PBW). Once the PBW of the premature infant approaches 1.0 kg (2.2 lb), this restriction disappears.

After entering PBW, review and change all settings as needed.

The correlation function PBW = height was derived from the sources referenced. For subjects whose body weight/height data define the range of PBWs

that include the 20- to 23-week gestational-age neonates and the young male and female adolescent adults at the foot of the ARDS tables, their PBW values were taken as the 50th percentile numbers in the Fenton tables and the CDC and NCHS charts and tables, respectively. Note that the Fenton tables provided the exclusive information for premature and infant data between 20 weeks and 50 weeks of fetal and gestational growth.[1][2][3]

Note:
Any repeated values noted in the tables are the result of decimal rounding.

4.7 Non-invasive Ventilation (NIV)

Non-invasive ventilation (NIV) is used when the clinician determines a mask or other non-invasive patient interface rather than an endotracheal tube would result in the desired patient outcome.

4.7.1 NIV Intended Use

NIV is intended for use by neonatal, pediatric, and adult patients possessing adequate neural-ventilatory coupling and stable, sustainable, respiratory drive.

4.7.2 NIV Breathing Interfaces

Covidien has successfully tested the following non-vented interfaces with NIV:

- Full-face Mask: Puritan Bennett® Benefit Full Face Mask (large, part number 4-005253-00), ResMed Mirage™ Non-Vented Full Face Mask (medium)
- Nasal Mask: ResMed Ultra Mirage™ Non-vented Mask (medium)
- Infant Nasal Prongs: Sherwood Davis & Geck Argyle® CPAP Nasal Cannula (small), Hudson RCI® Infant Nasal CPAP System (No. 3)
- Uncuffed neonatal ET tube: Mallinckrodt Uncuffed Tracheal Tube, Murphy (3.0 mm)

1. Fenton TR, BMC Pediatrics 2003, 3:13. http://www.biomedcentral.com/1471-2431/3/13.
2. Hamill, PV V. 1977 NCHS growth curves for children birth to 18 years for the United States: National Center for Health Stat (Vital and Health Statistics: Series 11, Data from the National Health Survey; no. 165) (DHEW publication; (PHS) 78 - 1650). 1977.
3. Kuczmarski RJ, Ogden CL, Guo SS, et al. 2000 CDC growth charts for the United States: Methods and development. National Center for Health Statistics. Vital Health Stat 11(246). 2002.

WARNING:
Use only non-vented patient interfaces with NIV. Leaks associated with vented interfaces could result in the ventilator's inability to compensate for those leaks, even if Leak Sync is employed.

WARNING:
Full-face masks used for non-invasive ventilation should provide visibility of the patient's nose and mouth to reduce the risk of emesis aspiration.

WARNING:
When Using NIV, the patient's exhaled tidal volume (V_{TE}) could differ from the ventilator's monitored patient data V_{TE} reading due to leaks around the interface. To avoid this, ensure Leak Sync is installed.

4.7.3 NIV Setup

NIV can be initiated from either the New Patient Setup screen during Vent start-up or while the patient is being ventilated invasively. Reference the table below for using NIV patient setup information.

Table 4-2. Setting Up a Patient for NIV

To set up a new patient	To set up a patient currently being ventilated
1. Turn the ventilator on. 2. Select New Patient. 3. Enter patient's PBW or gender and height. 4. Touch NIV vent type. 5. Select mode. 6. Select mandatory type. 7. Complete ventilator settings, including apnea and alarm settings.	1. Touch or swipe the menu tab on the left side of the GUI. 2. Touch *Vent Setup*. 3. Perform steps 4 through 7 as if setting the ventilator up for a new patient. 4. Review the settings, including apnea and alarm settings and change if necessary.

4.7.4 Conversion from INVASIVE to NIV Vent Type

WARNING:
For proper ventilation when changing the Vent Type on the same patient, review the automatic settings changes described. Adjust appropriately based on the relevant tables.

Some ventilator settings available during INVASIVE ventilation are not available during NIV. Reference the following table for automatic settings changes when changing vent type from INVASIVE to NIV.

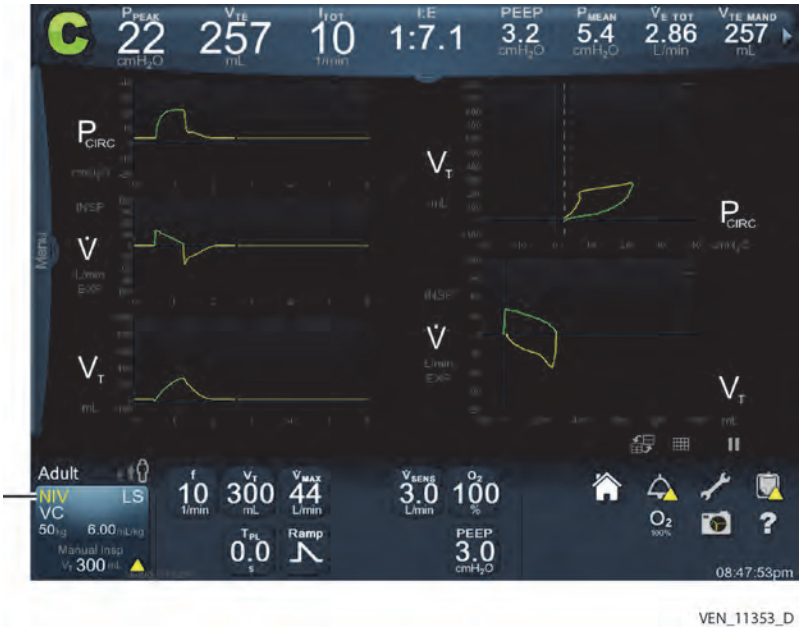
Table 4-3. INVASIVE to NIV on Same Patient

Current INVASIVE setting	New NIV setting
Breath Mode: BiLevel	Breath mode: A/C
Breath Mode: SIMV or SPONT	High $T_{I\ SPONT}$ ($\overline{\uparrow}T_{I\ SPONT}$) limit setting available
Mandatory Type: VC+	Mandatory type: Neonatal: PC Adult/Pediatric: VC
Spontaneous Type: Any type except PS	Spontaneous type: PS
Trigger type: Pressure	Trigger type: Flow (Flow triggering is the only allowable trigger type during NIV)
Alarm settings: $\downarrow P_{PEAK}$ (if applicable), $\downarrow \dot{V}_{E\ TOT}$, $\downarrow V_{TE\ MAND}$, $\downarrow V_{TE\ SPONT}$, INSPIRATION TOO LONG (not user-settable)	Alarm settings: $\downarrow P_{PEAK}$, $\downarrow \dot{V}_{E\ TOT}$, $\downarrow V_{TE\ MAND}$, $\downarrow V_{TE\ SPONT}$ default to NIV new patient values. Reference *Alarm Settings Range and Resolution*, p. 11-17. INSPIRATION TOO LONG alarm not available.
D_{SENS}	D_{SENS} setting defaults to OFF if Leak Sync is enabled.

Note:
In any delivered spontaneous breath, either INVASIVE or NIV, if Pressure Support is set to 0 cmH_2O, there is always a target inspiratory pressure of 1.5 cmH_2O applied.

When in NIV, the Vent Setup button's appearance changes, letting the operator know the vent type is NIV.

Figure 4-9. Vent Setup Button "NIV" Indicating NIV vent type



4.7.5 Conversion from NIV to INVASIVE Vent Type

The table below shows automatic settings changes made when changing vent type from NIV to INVASIVE.

Table 4-4. NIV to INVASIVE on Same Patient

Current NIV setting	New INVASIVE setting
Ventilator settings: $\overline{\uparrow}T_{I\ SPONT}$	N/A
Alarm settings: $\downarrow P_{PEAK}$, $\downarrow \dot{V}_{E\ TOT}$, $\downarrow V_{TE\ MAND}$, $\downarrow V_{TE\ SPONT}$	Alarm settings: Default to new patient values dependent upon selected INVASIVE ventilator settings. Reference *Alarm Settings Range and Resolution*, p. 11-17. INSPIRATION TOO LONG alarm becomes available.
D_{SENS}	D_{SENS} setting defaults to INVASIVE new patient value. Reference *Ventilator Settings Range and Resolution*, p. 11-8.

4.7.6 High Spontaneous Inspiratory Time Limit Setting

NIV includes a setting in SIMV or SPONT modes for High Spontaneous Inspiratory Time limit ($\overline{\uparrow}T_{I\ SPONT}$). When a patient's inspiratory time reaches or exceeds the set limit, the ventilator transitions from inspiration to exhalation, and the $\uparrow T_{I\ SPONT}$ symbol appears at the lower left on the GUI screen, indicating the ventilator has truncated inspiration (shown below). The $\overline{\uparrow}T_{I\ SPONT}$ setting does not restrict changes to PBW; if the PBW is decreased, $\overline{\uparrow}T_{I\ SPONT}$ may decrease automatically to remain within its allowable limits.

Figure 4-10. $\overline{\uparrow}T_{I\ SPONT}$ Indicator



WARNING:
No audible alarm sounds in conjunction with the visual $\overline{\uparrow}T_{I\ SPONT}$ indicator, nor does the indicator appear in any alarm log or alarm message.

It is possible the target inspiratory pressure may not be reached if the $\overline{\uparrow}T_{I\ SPONT}$ setting is not long enough, or if system leaks are so large as to cause the ventilator to truncate the breath at the maximum allowable$\overline{\uparrow}T_{I\ SPONT}$ setting.

Note:
To reduce the potential for not reaching the target pressure, minimize the leaks in the system and increase the Rise time % and/or decrease the E_{SENS} setting, if appropriate.

4.7.7 NIV Apnea Setup

Set the patient's apnea parameters as described. Reference *Apnea Settings*, p. 4-15. NIV does not change the way apnea parameters are set.

4.7.8 NIV Alarm Settings

The system initially sets most alarm settings based on the patient's PBW. Review all alarm settings, and change as necessary, but startup does not require confirmation of the settings.

Figure 4-11. Default NIV Alarm Settings



Touch the Alarms tab at any time during ventilation to show the current limits and the monitored patient value shown in white on the indicating arrows for each alarm. If an alarm is occurring, the indicator LED color changes based on alarm priority Reference *Alarm Prioritization*, p. 6-16 for colors and meanings

of alarms and their priorities.

Note:
The upper and lower limits of an alarm cannot conflict with each other.

Note:
The upper limits for the spontaneous exhaled tidal volume and mandatory exhaled tidal volume alarms are always the same value. Changing the upper limit of one alarm automatically changes the upper limit of the other.

4.8 Manual Inspiration



A manual inspiration is an operator-initiated mandatory (OIM) inspiration. When the operator presses the Manual inspiration key, the ventilator delivers the currently specified apnea breath setting for spontaneous breaths, or the currently specified mandatory breath setting for mandatory breaths, either volume- or pressure-based. A volume-based manual inspiration is compliance-compensated. Pressing the Manual inspiration key while in BiLevel mode will transition from T_H to T_L or T_L to T_H depending on when in the breath cycle the key was pressed.

4.9 Respiratory Mechanics Maneuvers

To access respiratory mechanics maneuvers

1. Touch or swipe *Menu* tab on the left side if the GUI.
2. Touch *RM*.

Figure 4-12. RM in Menu Tab



3. Touch the particular tab for the desired maneuver.

Figure 4-13. Respiratory Maneuver Tabs



4. Follow the prompts on the GUI screen.

5. Accept or reject the maneuver results. If the result is accepted, its value is saved.

4.9.1 Inspiratory Pause Maneuver

An inspiratory pause maneuver closes the inspiration and exhalation valves and extends the inspiratory phase of a single, mandatory breath for the purpose of measuring end inspiratory circuit pressure in order to calculate inspiratory Plateau Pressure (P_{PL}), lung Static Compliance (C_{STAT}), and Static Resistance (R_{STAT}) of the respiratory system. Pressures on either side of the artificial airway are allowed to equilibrate, which determines the pressure during a no-flow state. A request for an inspiratory pause is rejected during apnea ventilation, safety PCV, OSC, BUV, and in Stand-by state. Inspiratory pauses are allowed in A/C, SIMV, BiLevel and SPONT modes. If an inspiratory pause maneuver has already occurred during the breath, a second inspiratory pause maneuver is not allowed.

Inspiratory pauses can be classified as **automatic** or **manual**. The **automatic** inspiratory pause lasts at least 0.5 second but no longer than three seconds. A **manual** inspiratory pause starts by pressing and holding inspiratory pause key. The pause lasts for the duration of the key-press (up to seven seconds).

To perform an automatic inspiratory pause

1. Press and release the inspiratory pause key on the GUI bezel or touch and release *Start* if performing an inspiratory pause from the GUI screen as shown above. The ventilator performs the inspiratory pause maneuver and displays P_{PL}, C_{STAT}, and R_{STAT} along with the date and time.

2. Touch *Accept* or *Reject* to save or dismiss results. If *Accept* is touched, the results are displayed.

Cancel an automatic inspiratory pause maneuver by touching *Cancel* on the GUI screen.

To perform a manual inspiratory pause

1. Press and hold the inspiratory pause key on the GUI bezel or touch and hold *Start* on the GUI screen if performing an inspiratory pause from the GUI screen as shown above. The ventilator prompts that the maneuver has started, and to release to end the maneuver. The ventilator performs the inspiratory pause maneuver and displays P_{PL}, C_{STAT}, and R_{STAT}, along with the date and time.

2. Touch *Accept* or *Reject* to save or dismiss results. If *Accept* is touched, the results are displayed.

Cancel a manual inspiratory pause maneuver by releasing the Inspiratory Pause key.

4.9.2 Expiratory Pause Maneuver

An expiratory pause extends the expiratory phase of the current breath for the purpose of measuring end expiratory lung pressure ($PEEP_{TOT}$) or total PEEP. It has no effect on the inspiratory phase of a breath, and only one expiratory pause per breath is allowed. For I:E ratio calculation purposes, the expiratory pause maneuver is considered part of the exhalation phase.

During an expiratory pause, both inspiratory and exhalation valves are closed, allowing the pressures on both sides of the artificial airway to equilibrate. This allows intrinsic PEEP ($PEEP_I$) to be calculated. $PEEP_I$ is $PEEP_{TOT}$ minus the set PEEP level. An expiratory pause can be either automatically or manually administered, and is executed at the next mandatory breath in A/C, SIMV, or BiLevel modes. In SIMV, the breath cycle in which the pause becomes active (when the next scheduled ventilator initiated mandatory (VIM) breath occurs) will be extended by the amount of time the pause is active. For A/C and SIMV, the expiratory pause maneuver is scheduled for the next end-of-exhalation prior to a mandatory breath. In BiLevel the expiratory pause maneuver is scheduled for the next end-of-exhalation prior to a transition from P_L to P_H. During the expiratory pause maneuver, $PEEP_I$ and $PEEP_{TOT}$ equilibration time values are displayed and regularly updated because stabilization of one of these values can indicate the pause can be ended. During the expiratory pause, the Apnea Interval T_A is extended by the amount of time the pause is active. Expiratory pause requests are ignored if the ventilator is in apnea ventilation, safety PCV,OSC, BUV, and Stand-by state. Additionally, SEVERE OCCLUSION alarms are suspended during expiratory pause maneuvers. If flow triggering is active, backup pressure sensitivity (P_{SENS}) detects patient breathing effort.

Maximum duration for a **manual** expiratory pause is 15 seconds and three (3) seconds for an **automatic** expiratory pause.

During a manual or automatic expiratory pause, $PEEP_I$ and $PEEP_{TOT}$ appear on the GUI with the next VIM to allow the clinician to view when these values are stabilized, indicating the maneuver can be ended.

To perform an automatic expiratory pause

1. Press and release the expiratory pause key on the GUI or touch and release *Start* if performing the expiratory pause from the GUI screen. The ventilator performs the expiratory pause maneuver and displays a circuit pressure graph, $PEEP_{TOT}$, and $PEEP_I$, along with the date and time.

To perform a manual expiratory pause

1. Press and hold the expiratory pause key on the GUI bezel or touch and hold *Start* if performing the expiratory pause from the GUI screen. The ventilator prompts that the maneuver has started, and to release the button to end the maneuver. The ventilator performs the expiratory pause maneuver and displays a circuit pressure graph, $PEEP_{TOT}$, and $PEEP_I$, along with the date and time.

2. Accept or reject the pause results.

To cancel an expiratory pause maneuver

1. Touch *Cancel* on the GUI screen.

4.9.3 Other Respiratory Maneuvers

To perform other respiratory maneuvers, touch the corresponding tab on the desired maneuver, and follow the prompts on the GUI screen.

4.10 Oxygen Sensor Function

The ventilator's oxygen sensor monitors O_2%. This cell is mounted in the inspiratory module in the BDU and monitors the percentage of oxygen in the mixed gas delivered to the breathing circuit (it may not reflect the actual oxygen concentration in the gas the patient inspires).

Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* for instructions on replacing the O_2 sensor.

New patient default O_2% settings are as follows:

- O_2 sensor — enabled
- Neonatal — 40% O_2
- Pediatric/adult — 100% O_2

Note:
The oxygen sensor has three states: Enabled, Disabled, and Calibrate. The oxygen sensor is enabled at ventilator startup regardless if New Patient or Same Patient setup is selected.

To enable, or disable the O_2 sensor



1. Touch *Vent Setup*.
2. Touch the *More Settings* tab. The more settings screen appears.

Figure 4-14. More Settings Screen with O_2 Sensor Enabled



3. Touch the button corresponding to the desired O_2 sensor function (*Enable* or **Disable**).
4. Touch *Accept*.

4.10.1 Oxygen Sensor Life

The O_2% setting can range from room air (21% O_2) up to a maximum of 100% oxygen. The sensor reacts with oxygen to produce a voltage proportional to the partial pressure of the mixed gas. Since ambient atmosphere contains approximately 21% oxygen, the sensor constantly reacts with oxygen and

always produces a voltage. The useful life of the cell can also be shortened by exposure to elevated temperatures and pressures. During normal use in the ICU, the oxygen sensor lasts for approximately one year — the interval for routine preventive maintenance.

Because the oxygen sensor constantly reacts with oxygen, it requires periodic calibration to prevent inaccurate O_2% alarm annunciation. Once a calibrated oxygen sensor and the ventilator reach a steady-state operating temperature, the monitored O_2% will be within three percentage points of the actual value for at least 24 hours. To ensure the oxygen sensor remains calibrated, recalibrate the oxygen sensor at least once every 24 hours.

Typically, the clinician uses an O_2 analyzer in conjunction with the information given by the ventilator. If a NO O_2 SUPPLY alarm occurs, compare the O_2 analyzer reading with the ventilator's O_2 reading for troubleshooting purposes. The ventilator automatically switches to delivering air, only (21% oxygen).

4.10.2 Oxygen Sensor Calibration

The oxygen sensor should be calibrated every 24 hours and before use. The calibration function provides a single-point O_2 sensor calibration.

To calibrate the O_2 sensor



1. Touch *Vent Setup*.
2. Touch *More Settings*.
3. Touch the *Calibrate* for the O_2 sensor. The oxygen sensor calibrates within two minutes. Reference *More Settings Screen with O_2 Sensor Enabled*, p. 4-33.

4.10.3 Oxygen sensor calibration testing

To test the O_2 sensor calibration

1. Connect the ventilator's oxygen hose to a known 100% O_2 source (for example, a medical-grade oxygen cylinder).



2. Calibrate the oxygen sensor as described above.

3. Connect the ventilator oxygen hose to another known 100% O_2 source (for example, a second medical-grade oxygen cylinder).
4. Set O_2% to each of the following values, and allow one minute after each for the monitored value to stabilize: 21%, 40%, 90%
5. Watch the GUI screen to ensure the value for O_2 (delivered O_2%) is within 3% of each setting within one minute of selecting each setting.

4.11 Ventilator Protection Strategies

The ventilator incorporates a number of strategies to support patient safety. These include Power On Self-Test (POST), SST and a new strategy called ***Ventilation Assurance*** which provides alternate means of ventilation in the case of certain serious faults in the breath delivery system. The descriptions below detail the system response to potential failures.

4.11.1 Power on Self Test (POST)

The first strategy is to detect potential problems before the ventilator is placed on a patient. POST checks the integrity of the ventilator's electronics and prevents ventilation if a critical fault is found. (Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* for a complete description of POST). POST may detect major or minor system faults which manifest themselves as Device Alerts. Reference *DEVICE ALERT Alarm*, p. 6-36 for more information.

4.11.2 Technical Fault

A technical fault occurs if a POST or background test has failed. Reference *Power On Self Test (POST)*, p. 10-76. Based on the test that failed, the ventilator will either ventilate with current settings, ventilate with modified settings, or enter the Vent Inop state. A technical fault cannot be cleared by pressing the alarm reset key. It can only be cleared by correcting the fault that caused it or if alarm reset criteria have been met.

4.11.3 SST

In addition to characterizing the ventilator breathing circuit, SST performs basic checks on the ventilator's pneumatic system including the breath delivery

PSOL, the Flow Sensors and the Exhalation Valve. Faults detected during SST must be corrected before ventilation can be started.

4.11.4 Procedure Error

A procedure error occurs when the ventilator senses a patient connection before ventilator setup is complete. The ventilator provides ventilatory support using default Safety Pressure Controlled Ventilation (Safety PCV) settings. Reference *Safety PCV Settings*, p. 10-72

4.11.5 Ventilation Assurance

During ventilation, the ventilator performs frequent background checks of its breath delivery sub-system (Reference *Safety Net*, p. 10-71). In the event that certain critical components in the pneumatics fail, Ventilation Assurance provides for continued ventilatory support using one of three Backup Ventilation (BUV) strategies, bypassing the fault to maintain the highest degree of ventilation that can be safely delivered (Reference *Background Diagnostic System*, p. 10-74 for a full description of the Backup Ventilation strategies).

Note:
Do not confuse BUV with Safety PCV, which occurs when a patient is connected before ventilator setup is complete, or with Apnea ventilation, which occurs in response to patient apnea.

4.11.6 Safety Valve Open (SVO)

In the event of a serious fault occurring that cannot be safely bypassed, the ventilator, as a last resort, reverts to a Safe State. In Safe State, the ventilator opens the Safety Valve and the Exhalation Valve, allowing the patient to breathe room air (if able to do so), provided the patient circuit is not occluded, and the inspiratory PSOL valve is closed. During SVO, the patient (if connected) can breathe room air through the safety valve after it releases pressure in the patient circuit. The patient exhales through the exhalation valve with minimal resistance and the exhalation valve also acts like a check valve, limiting gas from being drawn in through the expiratory filter or expiratory limb of the circuit. SVO conditions are logged into the event and alarm logs as are the events leading to the SVO condition. If the condition causing SVO clears, the ventilator clears the SVO state. Patient data do not display on the GUI, but graphics are still plotted. During SVO, the ventilator ignores circuit occlusions and dis-

connects. If the condition causing SVO can only be corrected by servicing the ventilator, the SVO alarm cannot be reset by pressing the alarm reset key.

4.11.7 Ventilator Inoperative (Vent Inop)

Vent Inop occurs when the ventilator detects a catastrophic error which prevents all other safety states from operating. Vent Inop limits pressure to the patient as the ventilator enters the SVO state, disables (closes) the gas mixing PSOL valves, and purges the gas mixing system accumulator. The safety valve is opened and a Vent Inop indicator illuminates and a high priority alarm annunciates from the primary alarm, and the secondary alarm (continuous tone) is activated. The ventilator can only exit the Vent Inop state by power cycling and successfully passing EST. The Vent Inop alarm cannot be reset with the alarm reset key. All detection and annunciation of patient data alarm conditions is suspended.

During a Vent Inop condition, the inspiratory and expiratory pressure drop measured at the patient wye does not exceed 6.0 cmH_2O at 30 L/min.

4.12 Ventilator Shutdown

When the ventilator power switch is turned OFF, the ventilator executes an orderly shutdown routine, saving patient data before removing power. If the ventilator detects a patient connected when the power switch is turned OFF, a high priority alarm is annunciated and a banner on the display requires the operator to confirm that a power down was requested. Only after the operator confirms will the ventilator execute the shutdown command.

All logs are retained in the ventilator's memory upon ventilator shutdown. When the logs reach the maximum number of entries, the oldest values are overwritten with new values. Reference *Ventilator Logs*, p. 8-2 for information on ventilator logs.

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5 Product Data Output

5.1 Overview

This chapter describes the features of the Puritan Bennett™ 980 Series Ventilator designed to provide output to the clinician. This includes language, methods of displaying and transferring data, types of displayed data, and types of external device ports. Connectivity to an external patient monitoring system is also included.

5.2 Language

The language used on the ventilator is configured at the factory.

5.3 Data Display

Displayed data are updated in real-time. The practitioner can display up to 60 seconds of waveform data and pause and capture up to two loops using the screen capture function. The operator can pause the displays and when the displays are paused, a cursor appears with the relevant numeric values for the intersecting points of the cursor and waveform or loop. The scalar waveform contains a single value, but loops contain both x- and y-axis data. The operator can move the cursor along the waveform or loop using the knob, and read the corresponding data. Reference *Waveforms*, p. 3-44 for details regarding configuring and displaying waveforms.

5.4 Data Transfer

Data from the ventilator can be accessed via USB or RS-232 connectors. The following data are available for downloading via connection to a remote device or flash drive:

- Waveform images (screen capture function): USB port

- Waveform data: RS-232 port, USB port with USB to serial conversion capability (per Comm port configuration)
- Results from DCI commands: RS-232 port, USB port with USB to serial conversion capability (per Comm port configuration)

5.4.1 GUI Screen Capture

Caution:
The USB interface should be used for saving screen captures and interfacing with an external patient monitor. It should not be used to provide power to other types of devices containing a USB interface.

Covidien recommends a minimum 128 MB flash drive storage device formatted in the 32-bit file format.

To capture GUI screens

1. Navigate to the desired screen from which you wish to capture an image (for example, the waveforms screen). There is no need to pause the waveform before performing the screen capture.



2. Touch the screen capture icon in the constant access icons area of the GUI screen. If desired, navigate to another screen and repeat steps 1 and 2 for up to ten (10) images. If another image is captured, increasing the queue to eleven images, the newest image overwrites the oldest image so there are always only ten images available.

Note:
If the camera icon appears dim, it means that the screen capture function is currently processing images and is unavailable. When processing is finished, the camera icon is no longer dim and the screen capture function is available.

To transfer the captured images to a USB storage device

1. Swipe the Menu on the left side of the GUI. Reference *Open Menu Tab*, p. 4-11.
2. Touch *Screen Capture*. A list of screen captures appears, identified by time and date. A slider also appears if more images than shown are present.
3. Insert a passive USB storage device (flash drive) into one of the USB ports at the rear of the ventilator. Reference *Port Locations*, p. 5-18. If more than one USB storage device is installed in the ventilator, touch the button of the destination USB device where the image will be copied.

4. In the list of images, touch the image name.
5. Touch Copy. The image is stored on the destination USB storage device.
6. Alternatively, touch Select All, and all images in the list are stored on the USB device and which can then be viewed and printed from a personal computer.

Note:
The file format of screen captures is .PNG.

5.4.2 Communication Setup

To specify the communication configuration for the ventilator

1. Touch the Configure icon in the constant access icons area of the GUI. A menu appears with several tabs.
2. Touch *Comm Setup* tab. The Comm Setup screen appears allowing three (3) ports that can be configured. These ports can be designated as DCI, Philips, Spacelabs, or Waveforms.

Note:
Waveforms can be selected on any port, but only on one port at a time.

Figure 5-1. Comm Setup Screen



5.4.3 Comm Port Configuration

Configuring the Comm port allows the ventilator to communicate with devices listed in the Comm Setup screen, or to capture waveform data (in ASCII format) from the ventilator.

To configure Comm ports

1. Touch COM1, COM2, or COM3.
2. Turn the knob indicating the desired device configuration.
3. Select the desired baud rate. If waveforms was selected, the baud rate automatically becomes configured to 38400.
4. Select 7 or 8 data bits.
5. Select parity of even, odd, or none if data bits = 8.

Connect the device to the previously configured port. Reference *Port Locations*, p. 5-18 for a description and the locations of the Comm ports.

Note:
When a USB port is configured as a Comm port, it is necessary to use a USB-to-serial adapter cable. This adapter must be based on the chipset manufactured by Prolific. For further information, contact your Covidien representative.

Selecting waveforms when configuring a Comm port allows the ventilator to continuously transmit pressure, flow, and sequence numbers in ASCII format from the selected serial port, at a baud rate of 38400 bits/s, and the operator-selected stop bits, and parity. A sample of pressure and flow readings is taken every 20 *ms*. This sample of readings is transmitted on the selected serial port at the end of each breath at breath rates of 10/min and higher. For longer duration breaths, at least the first eight seconds of the breath is transmitted. The format of the data is as follows: The beginning of inspiration is indicated by "BS, S:nnn,<LF>" where 'BS' identifies the Breath Start, 'S:nnn' is a sequence number incremented at every breath, and <LF> is a line feed character. The fff, and ppp fields show the breath flow and pressure data. The end of exhalation is indicated by: "BE<LF>" where 'BE' indicates Breath End, and <LF> is a line feed character.

5.4.4 Serial Commands

The ventilator system offers commands that allow communication to and from the ventilator using a Comm port. Commands to the ventilator from a remote device include:

- RSET: Reference *RSET Command*, p. 5-5
- SNDA: Reference *SNDA Command*, p. 5-6
- SNDF: Reference *SNDF Command*, p. 5-10

Note:
The ventilator responds only if it receives a carriage return <CR> after the command string.

5.4.5 RSET Command

The RSET command clears data from the ventilator receive buffer. The ventilator does not send a response to the host system. Enter the RSET command exactly as shown:

RSET<CR>

5.4.6 SNDA Command

The SNDA command instructs the ventilator to send information on ventilator settings and monitored patient data to the host system. Enter the SNDA command exactly as shown:

SNDA<CR>

When the ventilator receives the command SNDA<CR>, it responds with the code MISCA, followed by ventilator settings and monitored patient data information.

The MISCA response follows this format:

MISCA	**706**	**97**	**<STX>**	**FIELD 5, … FIELD 101,**	**<ETX>**	**<CR>**
1	2	3	4	5	6	7

1	Response code to SNDA command	5	Data field, left-justified and padded with spaces
2	Number of bytes between <STX> and <CR>	6	End of transmission (03 hex)
3	Number of data fields between <STX> and <ETX>	7	Terminating carriage return
4	Start of transmission (02 hex)		

Fields not available are marked as "Not used." Underscores represent one or more spaces that pad each character string.

The table below lists MISCA responses to SNDA commands.

Table 5-1. MISCA Response

Component	Description
MISCA	Response to SNDA command (5 characters)
706	The number of bytes between <STX> and <CR> (3 characters)
97	The number of fields between <STX> and <ETX> (2 characters
<STX>	Start of transmission character (02 hex)

Table 5-1. MISCA Response (Continued)

Component	Description
Field 5	Ventilator time (HH:MM_) (6 characters)
Field 6	Ventilator ID to allow external hosts to uniquely identify each Puritan Bennett™ 980 Ventilator (18 characters)
Field 7	Room number (6 characters)
Field 8	Date (MMM_DD_YYYY_) (12 characters)
Field 9	Mode (CMV___, SIMV__, CPAP__ or BILEVL) (CMV = A/C) setting (6 characters)
Field 10	Respiratory rate setting in breaths per minute (6 characters)
Field 11	Tidal volume setting in liters (6 characters)
Field 12	Peak flow setting in liters per minute (6 characters)
Field 13	O_2% setting (6 characters)
Field 14	Pressure sensitivity setting in cmH_2O (6 characters)
Field 15	PEEP or P_L (in BiLevel) setting in cmH_2O (6 characters)
Field 16	Plateau time in seconds (6 characters)
Field 17 - 20	Not used (6 characters)
Field 21	Apnea interval in seconds (6 characters)
Field 22	Apnea tidal volume setting in liters (6 characters)
Field 23	Apnea respiratory rate setting in breaths per minute (6 characters)
Field 24	Apnea peak flow setting in liters per minute (6 characters)
Field 25	Apnea O_2% setting (6 characters)
Field 26	Pressure support setting in cmH_2O (6 characters)
Field 27	Flow pattern setting (SQUARE or RAMP__) (6 characters)
Field 28 - 29	Not used (6 characters)
Field 30	Elevate O_2 state (ON____ or OFF___) (6 characters)
Field31 - 33	Not used (6 characters)
Field 34	Total respiratory rate in breaths per minute (6 characters)
Field 35	Exhaled tidal volume in liters (6 characters)
Field 36	Exhaled minute volume in liters (6 characters)
Field 37	Spontaneous minute volume in liters (6 characters)

Table 5-1. MISCA Response (Continued)

Component	Description
Field 38	Maximum circuit pressure in cmH_2O (6 characters)
Field 39	Mean airway pressure in cmH_2O (6 characters)
Field 40	End inspiratory pressure in cmH_2O (6 characters)
Field 41	Expiratory component of monitored value of I:E ratio, assuming inspiratory component of 1 (6 characters)
Field 42	High circuit pressure limit in cmH_2O (6 characters)
Field 43 - 44	Not used (6 characters)
Field 45	Low exhaled tidal volume limit in liters (6 characters)
Field 46	Low exhaled minute volume limit in liters (6 characters)
Field 47	High respiratory rate limit in breaths per minute (6 characters)
Field 48	High circuit pressure alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 49 - 50	Not used (6 characters)
Field 51	Low exhaled tidal volume (mandatory or spontaneous) alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 52	Low exhaled minute volume alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 53	High respiratory rate alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 54	No O_2 supply alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 55	No air supply alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 56	Not used (6 characters)
Field 57	Apnea alarm status (NORMAL, ALARM_, or RESET_) (6 characters)
Field 58 - 59	Not used (6 characters)
Field 60	Ventilator time (HH:MM_) (6 characters)
Field 61	Not used (6 characters)
Field 62	Date (MMM_DD_YYYY_) (12 characters)
Field 63	Static compliance (C_{STAT}) from inspiratory pause maneuver in mL/cmH_2O (6 characters)
Field 64	Static resistance (R_{STAT}) from inspiratory pause maneuver in $cmH_2O/L/s$ (6 characters)

Table 5-1. MISCA Response (Continued)

Component	Description
Field 65	Dynamic compliance (C_{DYN}) in mL/cmH_2O (6 characters)
Field 66	Dynamic resistance (R_{DYN}) in cmH_2O/L/s (6 characters)
Field 67	Negative inspiratory force (NIF) in cmH_2O (6 characters)
Field 68	Vital capacity (VC) in L (6 characters)
Field 69	Peak spontaneous flow (PSF) in L/min (6 characters)
Field 70	Ventilator-set base flow in liters per minute (6 characters)
Field 71	Flow sensitivity setting in L/min (6 characters)
Field 72 - 83	Not used (6 characters)
Field 84	End inspiratory pressure in cmH_2O (6 characters)
Field 85	Inspiratory pressure or P_H setting in cmH_2O (6 characters)
Field 86	Inspiratory time or T_H setting in seconds (6 characters)
Field 87	Apnea interval setting in seconds (6 characters)
Field 88	Apnea inspiratory pressure setting in cmH_2O (6 characters)
Field 89	Apnea respiratory rate setting in breaths per minute (6 characters)
Field 90	Apnea inspiratory time setting in seconds (6 characters)
Field 91	Apnea O_2% setting (6 characters)
Field 92	Apnea high circuit pressure limit in cmH_2O (6 characters)
Field 93	Alarm silence state (ON____ or OFF___) (6 characters)
Field 94	Apnea alarm status (NORMAL, ALARM_ or RESET_) (6 characters)
Field 95	Severe Occlusion/Disconnect alarm status (NORMAL, ALARM_ or RESET_) (6 characters)
Field 96	Inspiratory component of I:E ratio or High component of H:L (BiLevel) setting (6 characters)
Field 97	Expiratory component of I:E ratio setting or Low component of H:L (BiLevel) (6 characters)
Field 98	Inspiratory component of apnea I:E ratio setting (6 characters)
Field 99	Expiratory component of apnea I:E ratio setting (6 characters)

Table 5-1. MISCA Response (Continued)

Component	Description
Field 100	Constant during rate setting change for pressure control mandatory breaths (I-TIME or I/E___ or_____) (6 characters) (where _____ represents T_E or PCV not active)
Field 101	Monitored value of I:E ratio (6 characters)
<ETX>	End of transmission character (03 hex)
<CR>	Terminating carriage return

5.4.7 SNDF Command

SNDF is a command sent from an external host device to the ventilator system instructing it to transmit all ventilator settings data, monitored patient data, and alarm settings and occurrences. Enter the SNDF command exactly as shown:

SNDF<CR>

When the ventilator receives the command SNDF<CR>, it responds with the code MISCF, followed by ventilator settings, monitored patient data, and alarm information

The MISCF response follows this format:

MISCF	**1225***	**169**	**<STX>**	**FIELD 5, … FIELD 169,**	**<ETX>**	**<CR>**
1	2	3	4	5	6	7

1	Response code to SNDF command	5	Data field, left-justified and padded with spaces
2	Number of bytes between <STX> and <CR>	6	End of transmission (03 hex)
3	Number of data fields between <STX> and <ETX>	7	Terminating carriage return
4	Start of transmission (02 hex)	*	1229 if Philips is selected for serial port in communication setup

The table below lists MISCF responses to SNDF commands

Note:
Non-applicable fields will either contain zero or be blank.

Table 5-2. MISCF Response

Component	Description
MISCF	Response to SNDF command (5 characters)
1225*	Number of bytes between <STX> and <CR> (4 characters) *1229 if Phillips is selected for the Comm port in Communication Setup
169	Number of fields between <STX> and <ETX> (3 characters)
<STX>	Start of transmission character (02 hex)
Field 5	Ventilator time (HH:MM_) (6 characters)
Field 6	Ventilator ID to allow external hosts to uniquely identify each Puritan Bennett™ 980 Ventilator (18 characters)
Field 7	Date (MMM_DD_YYYY_) (12 characters)
Field 8	Vent Type (NIV_____ or INVASIVE_) (9 characters)
Field 9	Mode (A/C___, SIMV__, SPONT_ or CPAP) (6 characters)
Field 10	Mandatory Type (PC____, VC____, VC+___) (6 characters)
Field 11	Spontaneous Type (PS____, TC____, VS____, PA____ (6 characters)
Field 12	Trigger Type setting ($\dot{V}_{-TRIG}$, P_{-TRIG}) (6 characters)
Field 13	Respiratory rate setting in breaths/min (6 characters)
Field 14	Tidal volume (V_T) setting in L (6 characters)
Field 15	Peak flow ($\dot{V}_{MAX}$) setting in L/min (6 characters)
Field 16	O_2% setting (6 characters)
Field 17	Pressure sensitivity setting in cmH_2O (6 characters)
Field 18	PEEP/CPAP in cmH_2O (6 characters)
Field 19	Plateau setting in seconds (6 characters)
Field 20	Apnea interval setting in seconds (6 characters)
Field 21	Apnea tidal volume setting in L (6 characters)
Field 22	Apnea respiratory rate setting in breaths/min (6 characters)
Field 23	Apnea peak flow setting in L/min (6 characters)

Table 5-2. MISCF Response (Continued)

Component	Description
Field 24	Apnea O_2% setting (6 characters)
Field 25	PCV apnea inspiratory pressure setting in cmH_2O (6 characters)
Field 26	PCV Apnea Inspiratory Time setting in seconds (6 characters)
Field 27	Apnea flow pattern setting (SQUARE or RAMP) (6 characters)
Field 28	Apnea mandatory type setting (PC or VC) (6 characters)
Field 29	Inspiratory component of Apnea I:E ratio (if apnea mandatory type is PC) (6 characters)
Field 30	Expiratory component of Apnea I:E ratio (if apnea mandatory type is PC) (6 characters)
Field 31	Support pressure setting (cmH_2O)
Field 32	Flow pattern setting (SQUARE or RAMP) (6 characters)
Field 33	Elevate O_2 state (ON or OFF) (6 characters)
Field 34	High inspiratory pressure alarm setting ($\overline{\uparrow}P_{PEAK}$) in cmH_2O (6 characters)
Field 35	Low inspiratory pressure alarm setting ($\downarrow P_{PEAK}$) in cmH_2O or OFF (6 characters)
Field 36	High exhaled minute volume ($\overline{\uparrow}\dot{V}_{E\ TOT}$) alarm setting in L/min or OFF (6 characters)
Field 37	Low exhaled minute volume ($\downarrow\dot{V}_{E\ TOT}$) alarm setting in L/min or OFF (6 characters)
Field 38	High exhaled mandatory tidal volume ($\overline{\uparrow}V_{TE\ MAND}$) alarm setting in mL or OFF (6 characters)
Field 39	Low exhaled mandatory tidal volume ($\downarrow V_{TE\ MAND}$) alarm setting in mL or OFF (6 characters)
Field 40	High exhaled spontaneous tidal volume ($\overline{\uparrow}V_{TE\ SPONT}$ alarm setting in mL or OFF (6 characters)
Field 41	Low exhaled spontaneous tidal volume ($\downarrow V_{TE\ SPONT}$) alarm setting in mL or OFF (6 characters)
Field 42	High respiratory rate ($\overline{\uparrow}f_{TOT}$) alarm setting in breaths/min or OFF (6 characters)
Field 43	High inspired tidal volume ($\overline{\uparrow}V_{TI}$) alarm setting in mL (6 characters)
Field 44	Base flow setting in L/min (6 characters)
Field 45	Flow sensitivity ($\dot{V}_{SENS}$) setting in L/min (6 characters)

Table 5-2. MISCF Response (Continued)

Component	Description
Field 46	PCV inspiratory pressure (P_I) setting in cmH_2O (6 characters)
Field 47	PCV inspiratory time (T_I) setting in seconds (6 characters)
Field 48	Inspiratory component of I:E ratio setting or High component of H:L ratio setting (6 characters)
Field 49	Expiratory component of I:E ratio setting or Low component of H:L ratio setting (6 characters)
Field 50	Constant during rate change setting (I-time, I/E, or E-time) (6 characters)
Field 51	Tube ID setting in mm (6 characters)
Field 52	Tube Type setting (ET or TRACH) (6 characters)
Field 53	Humidification type setting (Non-heated exp tube, Heated exp tube, or HME) (18 characters)
Field 54	Humidifier volume setting in L (6 characters)
Field 55	O_2sensor setting (Enabled or Disabled) (9 characters)
Field 56	Disconnect sensitivity (D_{SENS}) setting in % or OFF (6 characters)
Field 57	Rise time % setting (6 characters)
Field 58	PAV+ percent support setting (6 characters)
Field 59	Expiratory sensitivity (E_{SENS}) setting in % or L/min for PAV+ breath type (6 characters)
Field 60	PBW setting in kg (6 characters)
Field 61	Target support volume ($V_{T\ SUPP}$) setting in L (6 characters)
Field 62	High pressure (P_H) setting (in BiLevel) in cmH_2O (6 characters)
Field 63	Low pressure (P_L) setting (in BiLevel) in cmH_2O (6 characters)
Field 64	High pressure time (T_H) setting (in BiLevel) in seconds (6 characters)
Field 65	High spontaneous inspiratory time limit ($\overline{\uparrow}T_{I\ SPONT}$) setting in seconds (6 characters)
Field 66	Circuit type setting (ADULT, PEDIATRIC, or NEONATAL) (9 characters)
Field 67	Low pressure time (T_L) setting (in BiLevel) in seconds (6 characters)
Field 68	Expiratory time (T_E) setting in seconds (6 characters)
Field 69	End inspiratory pressure ($P_{I\ END}$) in cmH_2O (6 characters)

Table 5-2. MISCF Response (Continued)

Component	Description
Field 70	Respiratory rate (f_{TOT}) in breaths/min (6 characters)
Field 71	Exhaled tidal volume (V_{TE}) in L (6 characters)
Field 72	Patient exhaled minute volume ($\dot{V}_{E\ TOT}$) in L/min (6 characters)
Field 73	Peak airway pressure (P_{PEAK}) in cmH_2O (6 characters)
Field 74	Mean airway pressure (P_{MEAN}) in cmH_2O (6 characters)
Field 75	Expiratory component of monitored value of I:E ratio, assuming inspiratory component of 1 (6 characters)
Field 76	I:E ratio (6 characters)
Field 77	Delivered O_2% (6 characters)
Field 78	Inspired tidal volume (V_{TI}) in L (6 characters)
Field 79	Intrinsic PEEP ($PEEP_I$) in cmH_2O (6 characters)
Field 80	Estimated total resistance (R_{TOT}) in cmH_2O/L/s (6 characters)
Field 81	Estimated patient resistance (R_{PAV}) in cmH_2O/L/s (6 characters)
Field 82	Estimated patient elastance (E_{PAV}) in cmH_2O/L (6 characters)
Field 83	Estimated patient compliance (C_{PAV}) in mL/cmH_2O (6 characters)
Field 84	Not used
Field 85	Rapid shallow breathing index (f/V_T) (6 characters)
Field 86	Spontaneous percent inspiratory time (T_I/T_{TOT}) (6 characters)
Field 87	Monitored PEEP in cmH_2O (6 characters)
Field 88	Spontaneous inspiratory time ($T_{I\ SPONT}$) in seconds (6 characters)
Field 89	Exhaled spontaneous minute volume ($\dot{V}_{E\ SPONT}$) in L/min (6 characters)
Field 90	Intrinsic PEEP ($PEEP_I$) from expiratory pause maneuver in cmH_2O (6 characters)
Field 91	Total PEEP ($PEEP_{TOT}$) from expiratory pause maneuver in cmH_2O (6 characters)
Field 92	Static compliance (C_{STAT}) from inspiratory pause maneuver in mL/cmH_2O (6 characters)
Field 93	Static resistance (R_{STAT}) from inspiratory pause maneuver in cmH_2O/L/s (6 characters)

Table 5-2. MISCF Response (Continued)

Component	Description
Field 94	Plateau pressure (P_{PL}) from inspiratory pause maneuver in cmH_2O (6 characters)
Field 95	High spontaneous inspiratory time (ALERT_ or blank) (6 characters)
Field 96	Dynamic compliance (C_{DYN}) in mL/cmH_2O (6 characters)
Field 97	Dynamic resistance (R_{DYN}) in cmH_2O/L/s (6 characters)
Field 98	Peak spontaneous flow (PSF) in L/min (6 characters)
Field 99	Peak expiratory flow (PEF) in L/min (6 characters)
Field 100	End expiratory flow (EEF) in L/min (6 characters)
Field 101	Proximal Flow Sensor state) ON or OFF)
Field 102	Negative inspiratory force (NIF) in cmH_2O (6 characters)
Field 103	$P_{0.1}$ pressure change in cmH_2O (6 characters)
Field 104	Vital capacity (VC) in L (6 characters)
Field 105	Alarm Silence (ON or OFF) (6 characters)
Field 106	Apnea ventilation alarm* (6 characters)
Field 107	High exhaled minute volume alarm* ($\uparrow\dot{V}_{E\ TOT}$) (6 characters)
Field 108	High exhaled tidal volume alarm* ($\uparrow V_{TE}$) (6 characters)
Field 109	High O_2% alarm* (6 characters)
Field 110	High inspiratory pressure alarm* ($\uparrow P_{PEAK}$) (6 characters)
Field 111	High ventilator pressure alarm* ($\uparrow P_{VENT}$) (6 characters)
Field 112	High respiratory rate alarm* ($\uparrow f_{TOT}$) (6 characters)
Field 113	AC power loss alarm* (6 characters)
Field 114	Inoperative battery alarm* (6 characters)
Field 115	Low battery alarm* (6 characters)
Field 116	Loss of power alarm* (6 characters)
Field 117	Low exhaled mandatory tidal volume alarm* ($\downarrow V_{TE\ MAND}$) (6 characters)
Field 118	Low exhaled minute volume alarm* ($\downarrow\dot{V}_{E\ TOT}$) (6 characters)
* Possible responses are: NORMAL, LOW, MEDIUM, HIGH, or RESET.	

Table 5-2. MISCF Response (Continued)

Component	Description
Field 119	Low exhaled spontaneous tidal volume ($\downarrow V_{TE\ SPONT}$) alarm* (6 characters)
Field 120	Low O_2% alarm* (6 characters)
Field 121	Low air supply pressure alarm* (6 characters)
Field 122	Low O_2 supply pressure alarm* (6 characters)
Field 123	Reserved
Field 124	Disconnect alarm* (6 characters)
Field 125	Severe occlusion alarm* (6 characters)
Field 126	Inspiration too long alarm* (6 characters)
Field 127	Procedure error* (6 characters)
Field 128	Compliance limited tidal volume (V_T) alarm* (6 characters)
Field 129	High inspired spontaneous tidal volume* ($\downarrow T_{I\ SPONT}$) alarm (6 characters)
Field 130	High inspired volume* ($\uparrow V_{TI}$) alarm (6 characters)
Field 131	High compensation limit ($\uparrow P_{COMP}$) alarm* (6 characters)
Field 132	PAV+ startup too long alarm* (6 characters)
Field 133	PAV+ R and C not assessed alarm* (6 characters)
Field 134	Volume not delivered (VC+) alarm* (6 characters)
Field 135	Volume not delivered (VS) alarm* (6 characters)
Field 136	Low inspiratory pressure ($\downarrow P_{PEAK}$) alarm* (6 characters)
Field 137	Technical malfunction A5* (6 characters)
Field 138	Technical malfunction A10* (6 characters)
Field 139	Technical malfunction A15* (6 characters)
Field 140	Technical malfunction A20* (6 characters)
Field 141	Technical malfunction A25* (6 characters)
Field 142	Technical malfunction A30* (6 characters)
Field 143	Technical malfunction A35* (6 characters)
Field 144	Technical malfunction A40* (6 characters)
* Possible responses are: NORMAL, LOW, MEDIUM, HIGH, or RESET.	

Table 5-2. MISCF Response (Continued)

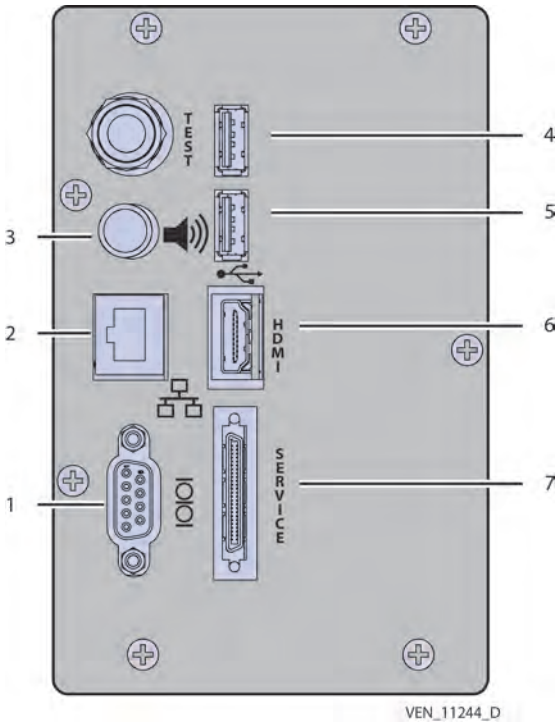
Component	Description
Field 145	Technical malfunction A45* (6 characters)
Field 146	Technical malfunction A50* (6 characters)
Field 147	Technical malfunction A55* (6 characters)
Field 148	Technical malfunction A60* (6 characters)
Field 149	Technical malfunction A65* (6 characters)
Field 150	Technical malfunction A70* (6 characters)
Field 151	Technical malfunction A75* (6 characters)
Field 152	Technical malfunction A80* (6 characters)
Field 153	Technical malfunction A85* (6 characters)
Field 154	Spontaneous tidal volume ($V_{TE\ SPONT}$) in liters (6 characters)
Field 155	Total work of breathing (WOB_{TOT}) in Joules/L (6 characters)
Field 156	Leak Sync state (9 characters) (ON, or OFF)
Field 157	%LEAK (6 characters)
Field 158	LEAK (6 characters)
Field 159	V_{LEAK} (6 characters)
Field 160	Prox Inop alarm* (ALARM or NORMAL)
Field 161 - 171	Reserved
<ETX>	End of transmission character (03 hex)
<CR>	Terminating carriage return
* Possible responses are: NORMAL, LOW, MEDIUM, HIGH, or RESET.	

5.5 Communication Ports

WARNING:
To avoid possible injury, only connect devices that comply with IEC 60601-1 standard to any of the ports at the rear of the ventilator, with the exception of passive memory storage devices (“flash drives”) and serial-to-USB adapter cables. If a serial-to-USB adapter cable is used, it must be connected to an IEC 60601-1-compliant device.

WARNING:
To avoid possible injury, do not connect a device that is attached to the patient to any of the non-clinical ports listed below when the ventilator is ventilating a patient.

Figure 5-2. Port Locations



1 RS-232 Port (COM 1)

2 Ethernet Port (non-clinical use)

3 Nurse call Port (remote alarm port)

4 USB Port (USB 1) (COM 2) (non-clinical use)

5 USB Port (USB 2) (COM 3) (non-clinical use)

6 HDMI Port (non-clinical use)

7 Service Port (non-clinical use)

5.5.1 Port Use

Reference *Data Transfer*, p. 5-1 for data transfer details.

RS-232 Port

To use the RS-232 port

1. Obtain a cable with a male DB-9 connector to connect to the RS-232 port on the ventilator.
2. Make the appropriate connection to a monitoring device. A gender changer, null modem cable or socket saver may be required. Consult with the institution's Information Technology professional as required.
3. Ensure to specify the baud rate, parity, and data bits in the ventilator communication setup to correctly match the parameters of the monitoring device.
4. A monitor designed to use this port is required for obtaining data from the ventilator. Set up the monitoring device to receive ventilator data. These data can include waveform data.
5. Program the remote device to send the appropriate RS-232 commands as described in the next section.

Reference Reference *MISCA Response*, p. 5-6 and Reference *MISCF Response*, p. 5-11 for MISCA and MISCF responses to SNDA and SNDF commands.

Ethernet Port

The Ethernet port is used by Service personnel for accessing various logs and updating ventilator software.

Nurse Call Port

A remote alarm or nurse call interface is available on the ventilator system which can be used to remotely annunciate the alarm status of the ventilator. Medium and high priority alarms are remotely annunciated. The nurse call connector is located at the back of the ventilator, as shown. Reference *Port Locations*, p. 5-18.

Reference the remote alarm manufacturer's instructions for use for information regarding proper nurse call connection.

USB Ports

The USB ports are used for screen captures, or receiving serial data when a USB port has been configured as a serial port. This is also known as transferring data via a serial-over-USB protocol. Reference *Communication Setup*, p. 5-3 for Comm setup configuration. Screen captures require an external USB memory storage device ("flash drive") for screen captures. Instructions for using this port for screen captures are given. Reference *To capture GUI screens*, p. 5-2.

HDMI Port

An external display can be used via connection with the HDMI port.

To use the HDMI port with an external display

1. Connect one end of an HDMI cable to the HDMI port at the back of the ventilator (item 6, above).
2. Connect the other end of the cable to the external display. An HDMI to DVI adapter may be used.
3. Turn the device on. The appearance of the GUI now displays on the external display device.

Service Port

The Service port is used by service personnel only.

5.6 Retrieving Stored Data



Ventilator data are stored in various logs, accessible using the logs icon. Some logs may be accessed during normal ventilation, and some are only available to Covidien personnel when the ventilator is in Service mode. Reference *Ventilator Logs*, p. 8-2 for more information on data stored in various logs.

5.7 Display Configurability

The operator can configure some ventilator parameters according to personal preference. Reference *Ventilator Configuration*, p. 3-35 for a table showing which parameters are configurable and by whom.

Reference *Preparing the Ventilator for Use*, p. 3-37 for information on configuring each display item.

5.8 Printing Data or Screen Captures

The ventilator cannot be connected directly to a printer.

Save screen captures to an external storage device, such as a USB flash drive, then print from a PC. Reference *GUI Screen Capture*, p. 5-2 for instructions on using the screen-capture feature.

5.9 Connectivity to External Systems

The ventilator is compatible with the Philips Medical IntelliVue MP50 and Spacelabs Ultraview patient monitoring systems.

Note:
Not all patient monitors are compatible with the Puritan Bennett 980 Series Ventilator.

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6 Performance

6.1 Overview

This chapter contains detailed information about Puritan Bennett™ 980 Series Ventilator performance including:

- Ventilator settings
- Alarm interpretation and alarm testing
- A detailed description of selected alarms
- Monitored patient data

6.2 System Options

Various software options are available for the ventilator. Details for each of these options are described in the appendices included in this manual.

6.3 Environmental Considerations

WARNING:
Use of the ventilator in altitudes higher or barometric pressures lower than those specified could compromise ventilator operation. Reference *Environmental Specifications*, p. 11-7 for a complete list of environmental specifications.

6.4 Ventilator Settings

Default ventilator settings are based on the circuit type selected during SST. A neonatal, pediatric or adult patient circuit can be used, and all accessories needed to ventilate the patient should be attached when SST is performed.

6.4.1 Ventilation Type

The clinician enters the vent type, specifying how the patient will be ventilated; invasively or non-invasively (NIV). The vent type optimizes the alarm limits for NIV patients, and disables some settings for NIV ventilation.

6.4.2 Mode

Available ventilation modes are mandatory (A/C) or spontaneous (SPONT) modes, as well as two "mixed" modes: SIMV and BiLevel.

- **A/C (Assist-Control) —** A/C mode guarantees delivery of a minimum number of mandatory breaths based on the frequency (*f)* set by the clinician. Breaths in A/C can be patient-initiated (PIM) or ventilator-initiated (VIM).
- **SPONT (Spontaneous) —** SPONT mode delivers only spontaneous breaths which are all patient-initiated.
- **SIMV (Synchronized Intermittent Mandatory Ventilation) —** SIMV is a mixed mode allowing both mandatory and spontaneous breaths. SIMV guarantees at least one mandatory breath per set breath cycle, which is either patient-initiated or ventilator-initiated. The mandatory type of an SIMV breath can be PC, VC, or VC+.
- **BiLevel —** BiLevel is also a mixed mode which overlays the patient's spontaneous breaths onto the breath structure for PC mandatory breaths. Two levels of pressure, P_L and P_H are employed. The breath cycle interval for both SIMV and BiLevel modes is 60/*f* where *f* is the respiratory rate set by the operator.
- **CPAP —** CPAP is available only when circuit type is neonatal and vent type is NIV. CPAP mode allows spontaneous breathing with a desired PEEP level. In order to limit inadvertent alarms associated with the absence of returned volumes in nasal CPAP breathing, CPAP does not make available exhaled minute volume and exhaled tidal volume alarm settings.

6.4.3 Breath Type

Mandatory breath types for A/C and SIMV modes include volume controlled (VC), pressure controlled (PC), or volume control plus (VC+) breath types, also called Mandatory Type.

- **VC (Volume Control) —** The ventilator delivers an operator-set tidal volume.
- **PC (Pressure Control) —** The ventilator delivers an operator-set pressure.
- **VC+ (Volume Control Plus) —** Volume control plus (a mandatory, pressure controlled breath type that does not restrict flow during the inspiratory phase, and

automatically adjusts the inspiratory pressure target from breath to breath to achieve the desired tidal volume despite changing lung conditions. Reference *Mandatory Breath Delivery*, p. 10-17 for more information on VC+.

Mandatory inspirations are triggered in the following ways

- **Pressure Trigger (P_{-TRIG}) —** Changes in circuit pressure cause the ventilator to deliver a breath. These pressure changes relate to the pressure sensitivity (P_{SENS}) set by the operator. If the patient makes an effort to inspire, the airway pressure drops. If the pressure drops by at least the value of P_{SENS}, the ventilator delivers a breath.

- **Flow Trigger ($\dot{V}_{-TRIG}$) —** Changes in flow in the circuit cause the ventilator to deliver a breath. The breath delivery and exhalation valve flow sensors measure gas flow in the ventilator breathing system. As the patient inspires, the delivered flow remains constant and the exhalation valve flow sensor measures decreased flow. When the difference between the two flow measurements is at least the operator-set value for flow sensitivity ($\dot{V}_{SENS}$), the ventilator delivers a breath.

- **Time Trigger —** The ventilator delivers a Ventilator Initiated Mandatory (VIM) breath after a specific amount of time elapses.

- **Operator Trigger (OIM) —** The operator presses the Manual inspiration key. An operator initiated mandatory breath is also called an OIM breath. During an OIM breath, the breath delivered is based on the current settings for a mandatory breath.

Spontaneous breathing modes such as SIMV, BiLevel, and SPONT include the following breath types (called Spontaneous Types):

- **PS (Pressure Support) —** The ventilator delivers an operator-set positive pressure above PEEP (or P_L in BiLevel) during a spontaneous breath. If SIMV is selected as the mode, PS is automatically selected for spontaneous type.

- **VS (Volume Support) —** The ventilator delivers an operator-set positive pressure above PEEP during a spontaneous breath and automatically adjusts the pressure level from breath to breath to consistently deliver the set tidal volume.

- **TC (Tube Compensation) —** Additional positive pressure delivered to the patient during spontaneous breaths to overcome resistance of the artificial airway.

- **PAV+ (Proportional Assist Ventilation)) —** A software option that allows the ventilator to reduce the work of breathing (WOB) by assisting the patient's inspiration by an operator-set amount proportional to the breathing effort generated by the patient. *Reference Appendix D* for more information on PAV+.

The inspiratory trigger methods for spontaneous breaths are

- **Pressure Trigger (P_{-TRIG}) —** Same as described for mandatory inspiration triggers.

- **Flow Trigger ($\dot{V}_{-TRIG}$) —** Same as described for mandatory inspiration triggers.
- **IE Sync Trigger —** When this software option is installed and the IE Sync trigger type is selected, triggering and cycling of spontaneous breaths occur based on the patient's intra-pleural pressure.
- **Operator Trigger (OIM) —** Since the operator can only initiate a mandatory breath by pressing the Manual inspiration key, spontaneous mode allows OIMs, but the breath delivered is based on the current apnea breath settings.

Reference *Inspiration — Detection and initiation*, p. 10-4 for details on the different trigger methods.

6.5 Alarms

This manual uses the following conventions when discussing alarms:

A description or name of an alarm without specifying the alarm setting is denoted with an upward or downward pointing arrow (↑ or ↓) preceding the specific alarm name. An alarm setting is denoted as an upward or downward pointing arrow with an additional horizontal limit symbol (↾ or ↿) preceding the specific alarm. Some alarm conditions actually limit breath delivery such as $\uparrow P_{PEAK}$ and $\uparrow V_{TI}$ by truncating inspiration and transitioning to the exhalation phase. These alarm conditions are denoted as alarm **limits**. Reference *Alarm Descriptions and Symbols*, p. 6-6.

6.5.1 Alarm Messages

Alarms are visually annunciated using an indicator on the top of the GUI, which has a 360° field of view. If an alarm occurs, this indicator flashes at a frequency and color matching the alarm priority. The alarms also appear as colored banners on the right side of the GUI screen. If an alarm occurs, this indicator appears in the color matching the alarm priority (yellow for low (!) and medium (!!) priority; red for high (!!!) priority. For technical alarm and non-technical alarm details, reference the respective tables on *p. 6-18* and *p. 6-29*.

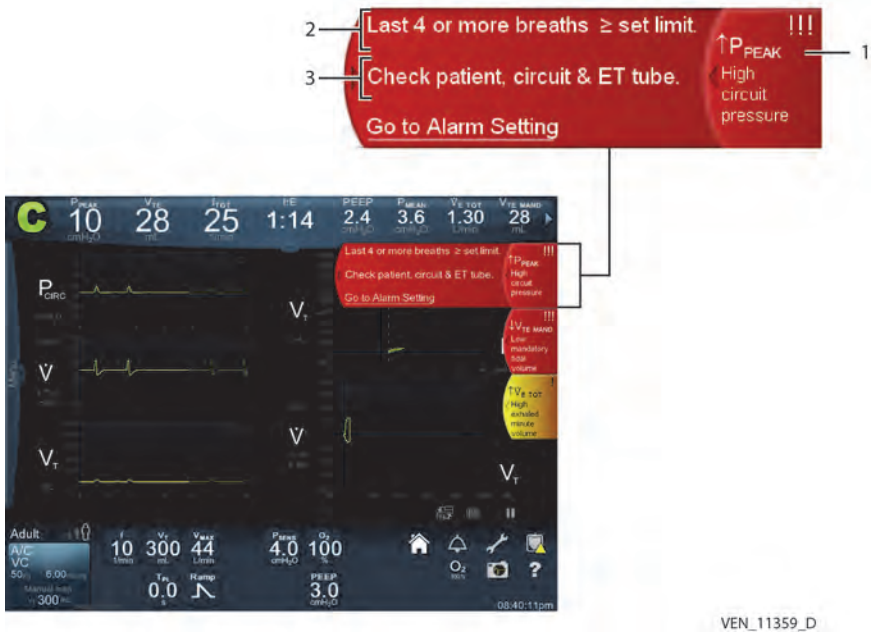
An alarm is defined as a ***primary alarm*** if it is the initial alarm. A ***dependent alarm*** arises as a result of conditions that led to the primary alarm. This is also referred to as an augmentation. An augmentation strategy is built into the ventilator software to handle occurrences where the initial cause of the alarm has the potential to precipitate one or more additional alarms. When an alarm occurs, any subsequent alarm related to the cause of this initial alarm aug-

ments the initial alarm instead of appearing on the GUI as a new alarm. The initial alarm's displayed analysis message is updated with the related alarm's information, and the Alarm Log Event column shows the initial alarm as **Augmented**.

A primary alarm consists of a ***base message***, ***analysis message***, and a ***remedy message***. The base message describes the primary alarm. The analysis message describes the likely cause of the alarm and may include alarm augmentations. The remedy message provides information on what to do to correct the alarm condition.

Alarm banners, when dragged leftward from the right side of the GUI, display messages for the indicated active alarms. The figure below, shows the alarm message format.

Figure 6-1. Alarm Message Format



1	Base message	3	Remedy message
2	Analysis message		

A ***latched alarm*** is one whose visual alarm indicator remains illuminated even if the alarm condition has autoreset. Latched alarm indicators are located on the sides of the omni-directional LED. A latched alarm can be manually reset by pressing the alarm reset key. If no alarms are active, the highest priority

latched alarm appears on the omni-directional LED on the GUI. A ***lockable alarm*** is one that does not terminate an active alarm silence function (it does not sound an audible alert during an active alarm silence function), while a non-lockable alarm cancels the alarm silence period and sounds an audible alert. All patient data alarms and the CIRCUIT DISCONNECT alarm are lockable alarms.

Note:
When a new lockable alarm occurs, the alarm will not start to sound audibly if the previous lockable alarm was silenced.

The following rules define how alarm messages are displayed:

- Primary alarms precede any dependent alarms.
- The system adds dependent alarms to the analysis messages of each active primary alarm with which they are associated. If a dependent alarm resets, the system removes it from the analysis message of the primary alarm.
- The priority level of a primary alarm is equal to or greater than the priority level of any of its active dependent alarms.
- An alarm cannot be a dependent alarm of any alarm that occurs subsequently.
- If a primary alarm resets, any active dependent alarms become primary unless they are also dependent alarms of another active primary alarm. This is due to different reset criteria for primary and dependent alarms.
- The system applies the new alarm limit to alarm calculations from the moment a change to an alarm limit is accepted.
- The priority level of a dependent alarm is based solely on its detection conditions (not the priority of any associated alarms.
- When an alarm causes the ventilator to enter OSC or safety valve open (SVO), the patient data display (including waveforms) is blanked. The elapsed time without ventilatory support (that is, since OSC or SVO began) appears on the GUI screen. If the alarm causing OSC or SVO is autoreset, the ventilator resets all patient data alarm detection algorithms.

Table 6-1. Alarm Descriptions and Symbols

Alarm description	Symbol
High compensation pressure	$\uparrow P_{COMP}$
High delivered oxygen percentage	$\uparrow O_2\%$

Table 6-1. Alarm Descriptions and Symbols (Continued)

Alarm description	Symbol
High exhaled minute volume	$\uparrow \dot{V}_{E\ TOT}$
High exhaled minute volume setting	$\overline{\uparrow} \dot{V}_{E\ TOT}$
High exhaled tidal volume	$\uparrow V_{TE}$
High exhaled tidal volume setting	$\overline{\uparrow} V_{TE}$
High inspired tidal volume limit	$\overline{\uparrow} V_{TI}$
High internal ventilator pressure	$\uparrow P_{VENT}$
High respiratory rate	$\uparrow f_{TOT}$
High respiratory rate setting	$\overline{\uparrow} f_{TOT}$
High spontaneous inspiratory time	$\uparrow T_{I\ SPONT}$
High spontaneous inspiratory time limit	$\overline{\uparrow} T_{I\ SPONT}$
High circuit pressure	$\uparrow P_{PEAK}$
High circuit pressure limit	$\overline{\uparrow} P_{PEAK}$
Low circuit pressure	$\downarrow P_{PEAK}$
Low circuit pressure setting	$\underline{\downarrow} P_{PEAK}$
Low exhaled mandatory tidal volume	$\downarrow V_{TE\ MAND}$
Low exhaled mandatory tidal volume setting	$\underline{\downarrow} V_{TE\ MAND}$
Low exhaled minute volume	$\downarrow \dot{V}_{E\ TOT}$
Low exhaled minute volume setting	$\underline{\downarrow} \dot{V}_{E\ TOT}$
Low exhaled spontaneous tidal volume	$\downarrow V_{TE\ SPONT}$
Low exhaled spontaneous tidal volume setting	$\underline{\downarrow} V_{TE\ SPONT}$
Low delivered oxygen percentage	$\downarrow O_2\%$

6.5.2 Alarm Reset Key



The alarm reset function can be used for any ***non-technical alarm***. Reference *Alarm Handling*, p. 6-15 for an explanation of **technical** vs. ***non-technical alarms***. Alarm reset reinitializes the algorithm the ventilator uses to initially detect the alarm except for A/C POWER LOSS, LOW BATTERY, NO AIR SUPPLY, NO O_2 SUPPLY, PROCEDURE ERROR alarms and active battery alarms. If the cause of the alarm still exists after the Alarm Reset key is pressed, the alarm becomes active again. The ventilator logs all actuations of the alarm reset key.

6.5.3 Alarm Silence Key



The alarm silence feature temporarily mutes the audible portion of an alarm for two minutes. After the two-minute period, if the alarm condition still exists, the alarm sounds again. Pressing the alarm silence key again re-starts the two minute interval during which an alarm is muted. An LED within the key illuminates and a count-down timer appears on the GUI next to an alarm silence indicator symbol, indicating an active alarm silence function. The alarm silence feature does not allow the audible alarm to be turned off; the audible portion of the alarm is temporarily muted for two minutes. The GUI's omni-directional LED flashes during an active alarm state and during an alarm silence period and its appearance changes with the priority if the alarm escalates. Pressing the Alarm Reset key cancels an Alarm Silence. If the condition that caused the alarm still exists, the alarm activates again.

6.5.4 Alarm Volume Key



An alarm volume key is available for setting the desired alarm volume. The alarm volume is automatically set to the factory default setting of 10 (maximum) or to the institutional default setting based on circuit type if it has been so configured. When setting the alarm volume, a sample tone is generated, allowing the practitioner to decide the appropriate alarm volume for the surrounding ambient conditions. If a high priority alarm occurs, the alarm volume increases one (1) increment from its current volume level if it is not acknowledged within 30 *s*. If a high priority alarm is not acknowledged within 60 *s*, the audible alarm volume escalates to its maximum volume.

Reference *To adjust alarm volume*, p. 3-41 for instructions on adjusting the alarm volume.

WARNING:
The audio alarm volume level is adjustable. The operator should set the volume at a level that allows the operator to distinguish the audio alarm above background noise levels. Reference *To adjust alarm volume*, p. 3-41.

6.5.5 Alarm Testing

Testing the alarms requires oxygen and air sources and stable AC power. Test the alarms at least every six months, using the procedures described.

Required Equipment

- Test lung (P/N 4-000612-00)
- Adult patient circuit

If the alarm does not annunciate as indicated, verify the ventilator settings and repeat the test. The alarm tests check the operation of the following alarms:

- CIRCUIT DISCONNECT
- LOW EXHALED MANDATORY TIDAL VOLUME ($\downarrow V_{TE\ MAND}$)
- LOW EXHALED TOTAL MINUTE VOLUME ($\downarrow \dot{V}_{E\ TOT}$)
- HIGH CIRCUIT PRESSURE ($\uparrow P_{PEAK}$)
- SEVERE OCCLUSION
- AC POWER LOSS
- APNEA
- LOW EXHALED SPONTANEOUS TIDAL VOLUME ($\downarrow V_{TE\ SPONT}$)
- NO O_2 SUPPLY
- LOW DELIVERED O_2% ($\downarrow O_2$%)
- HIGH DELIVERED O_2% ($\uparrow O_2$%)

Ventilator setup for alarms tests

1. Disconnect the patient circuit from the ventilator and turn the ventilator off for at least five minutes.
2. Turn the ventilator or on. The ventilator runs POST.

3. On the GUI, select NEW PATIENT.
4. Set up new patient using the following settings.

   PBW: 70 kg
   Vent type: INVASIVE
   Mode: A/C
   Mandatory type: VC
   Trigger type: $\dot{V}_{-TRIG}$
5. Set the following new patient settings

   f: 6.0 1/min
   $\mathbf{V_T}$: 500 mL
   $\dot{V}_{\mathbf{MAX}}$: 30 L/min
   $\mathbf{T_{PL}}$: 0 s
   Flow pattern: SQUARE
   $\dot{V}_{\mathbf{SENS}}$: 3 L/min
   $\mathbf{O_2\%}$: 21%
   PEEP: 5 cmH_2O
6. Set the following apnea settings

   $\mathbf{T_A}$: 10 s
   f: 6.0 1/min
   $\mathbf{O_2\%}$: 21%
   $\mathbf{V_T}$: 500 mL
7. Set the following alarm settings

   $\overline{\uparrow}\mathbf{P_{PEAK}}$: 70 cmH_2O
   $\boldsymbol{f}_{\mathbf{TOT}}$: OFF
   $\downarrow\dot{V}_{\mathbf{E\ TOT}}$: 1 L/min
   $\overline{\uparrow}\dot{V}_{\mathbf{E\ TOT}}$: 3.5 L/min
   $\downarrow\mathbf{V_{TE\ MAND}}$: 300 mL
   $\overline{\uparrow}\mathbf{V_{TE\ MAND}}$: OFF
   $\downarrow\mathbf{V_{TE\ SPONT}}$: OFF
   $\overline{\uparrow}\mathbf{V_{TE\ SPONT}}$: OFF

8. Set the graphics display to a volume-time plot (for use in the APNEA alarm test).

9. Connect an Adult patient circuit to the ventilator and attach a test lung to the patient wye.

Note:
To ensure proper test results, do not touch the test lung or patient circuit during the CIRCUIT DISCONNECT alarm test.

CIRCUIT DISCONNECT alarm test

1. Allow the ventilator to deliver at least four breaths. During the inspiratory phase of a breath, disconnect the inspiratory filter from the **To Patient** port. The ventilator annunciates a CIRCUIT DISCONNECT alarm after the inspiratory filter is disconnected.

2. Connect the inspiratory filter to the **To Patient** port to autoreset the alarm.

LOW EXHALED MANDATORY TIDAL VOLUME (↓$V_{TE\ MAND}$) alarm test

Set V_T to 225 mL. The ventilator annunciates a LOW EXHALED MANDATORY TIDAL VOLUME (↓$V_{TE\ MAND}$) alarm on the third consecutive breath after *Accept* is touched.

LOW EXHALED TOTAL MINUTE VOLUME (↓$\dot{V}_{E\ TOT}$) alarm test

Set ↓$\dot{V}_{E\ TOT}$ alarm limit to 3.45 L/min. The ventilator annunciates a LOW EXHALED TOTAL MINUTE VOLUME (↓$\dot{V}_{E\ TOT}$) alarm on the next breath after *Accept* is touched.

HIGH CIRCUIT PRESSURE (↑P_{PEAK}) alarm test

1. Make the following patient and alarm settings changes.

   V_T: 500 mL

   $\dot{V}_{MAX}$: 30 L/min

   ↑**P_{PEAK}**: 20 cmH_2O

2. After one breath, the ventilator annunciates a HIGH CIRCUIT PRESSURE (↑P_{PEAK}) alarm. If the alarm does not sound, check the patient circuit for leaks.

SEVERE OCCLUSION alarm test

1. Make the following alarm settings changes.

   ↑**P_{PEAK}**: 50 cmH_2O

2. Press the alarm reset key to reset all alarms.
3. Adjust D_{SENS} to the $\dot{v}_{MAX}$ setting.
4. Disconnect the ventilator breathing circuit from the FROM PATIENT port and block the gas flow.
5. While maintaining the occlusion, ensure the safety valve open indicator appears on the status display, the GUI shows the elapsed time without normal ventilation support, and the test lung inflates and deflates rapidly with small pulses as the ventilator delivers trial pressure-based breaths.
6. Press the alarm reset key to reset all the alarms.

AC POWER LOSS alarm test

1. Allow the ventilator to deliver at least four breaths, then disconnect the power cord from AC facility power. If any battery is charged, the GUI annunciates an AC POWER LOSS alarm. If less than ten minutes of battery backup are available, the GUI annunciates a LOW BATTERY alarm. If no battery power is available, the BDU annunciates a LOSS OF POWER alarm.
2. Connect the power cord to AC facility power. The AC POWER LOSS or LOW BATTERY alarm autoresets.

APNEA alarm test

1. Make the following alarm settings changes:

   $\overline{\uparrow}$**P_{PEAK}**: 70 cmH_2O

   Mode: SPONT

   Spontaneous type: PS

Note:
To avoid triggering a breath during the apnea interval, do not touch the test lung or patient circuit.

Note:
For the apnea alarm test, the exhaled tidal volume (V_{TE}) displayed in the patient data area must be greater than half the delivered volume shown on the volume-time plot in the graphics display in order for apnea to autoreset. Reference *Apnea Ventilation*, p. 10-41 for a technical description of apnea ventilation.

2. The GUI annunciates an APNEA alarm within 10 s after touching *Accept*.

3. Squeeze the test lung twice to simulate two subsequent patient-initiated breaths. The APNEA alarm autoresets.

4. Let the ventilator return to apnea ventilation.

LOW EXHALED SPONTANEOUS TIDAL VOLUME alarm test

1. Make the following patient and alarm settings changes

   Trigger type: P_{-TRIG}

   ⇑**P_{SENS}**: 4 cmH_2O

   ⇓**$V_{TE\ SPONT}$**: 2500 mL

2. Press the alarm reset key to reset the apnea alarm.

3. Slowly squeeze the test lung to simulate spontaneous breaths. The ventilator annunciates a LOW EXHALED SPONTANEOUS TIDAL VOLUME (⇓$V_{TE\ SPONT}$) alarm at the start of the fourth consecutive spontaneous inspiration.

4. Make the following patient settings changes:

   Mode: A/C

   ⇓**$V_{TE\ SPONT}$**: OFF

5. Press the alarm reset key to reset the ⇓$V_{TE\ SPONT}$ alarm.

NO O_2 SUPPLY alarm test

1. Disconnect the oxygen inlet supply. The ventilator annunciates a NO O_2 SUPPLY alarm within one breath.

2. Connect the oxygen inlet supply. The NO O_2 SUPPLY alarm autoresets within two breaths after oxygen is reconnected.

LOW DELIVERED O_2% and HIGH DELIVERED O_2% alarms tests

1. Make the following patient and alarm settings changes:

   P_{SENS}: 2 cmH_2O

   O_2%: 100%

2. Make the following apnea settings changes:

   T_A: 60 s

3. Attach the ventilator's oxygen gas hose to a known air supply (for example, a medical grade air cylinder) or a wall air outlet.

4. attach the ventilator's air gas hose to a known medical oxygen supply.
5. Observe the GUI screen. The delivered O_2% display should decrease, and the ventilator should annunciate a medium priority ↓O_2% alarm within 60 s and a high priority ↓O_2% alarm within two (2) minutes.
6. Set the O_2% to 21%.
7. Observe the GUI screen. The delivered O_2% display should increase, and the ventilator should annunciate a a medium priority ↑O_2% alarm within 60 s and a high priority ↑O_2% alarm within two (2) minutes.
8. Remove the air gas hose from the oxygen supply and reconnect the hose to a known medical air supply.
9. Remove the oxygen gas hose from the air supply and reconnect the hose to a known oxygen supply.
10. Press the alarm reset key to clear all alarms.

WARNING:
Before returning the ventilator to service, review all settings and set appropriately for the patient to be ventilated.

6.5.6 Viewing Alarms

When an alarm occurs, the omni-directional LED at the top of the GUI flashes in a color corresponding to the alarm priority, an audible series of tones sounds, and an alarm banner displays on the GUI. Reference *Areas of the GUI*, p. 4-3. When the alarm banner appears, it displays its base message. Touching the individual alarm causes an expanded explanation to appear, containing analysis and remedy messages, and may contain a link to the alarm log or the alarms settings screen. Touch the link to display requested information. The omni-directional LED remains steadily lit and may appear multicolored, meaning that multiple alarms with varying priority levels have occurred. During an event that causes multiple alarms, the ventilator simultaneously displays the two highest priority active alarms.

6.5.7 Alarm Delay

Determination of an Alarm Condition

The delay time from the moment the alarm condition first occurs until the alarm is annunciated is imperceptible.

Delay to/from a Distributed Alarm System

For alarm conditions relayed via the serial port, the overall delay is dependent upon the polling rate of the external device. The delay from the time the serial port is polled by the external device, until the alarm message leaves the serial port does not exceed 3 seconds. An example of an external device is a patient monitor.

6.5.8 Alarm Handling

Current alarm settings are saved in the ventilator's ***non-volatile memory (NVRAM)***. If the alarm settings are changed by another clinician, those settings become applicable. For example, there are no operator-selectable default alarm settings.

The ventilator system's alarm handling strategy is intended to

- Detect and call attention to legitimate causes for caregiver concern as quickly as possible, while minimizing nuisance alarms.
- Identify the potential cause and suggest corrective action for certain types of alarms. However, the clinician must make the final decision regarding any clinical action.
- Make it easy to discern an alarm's priority level.
- Allow quick and easy alarm setup.

Ventilator alarms are categorized as high priority, medium priority, or low priority, and are classified as technical or non-technical.

The ventilator is equipped with two alarms — the primary alarm and secondary alarm. The primary alarm annunciates high, medium, and low priority alarms when they occur. The secondary alarm (also named "immediate" priority in the table below) is a continuous tone alarm and annunciates during Vent Inop conditions or complete loss of power. This alarm is powered by a capacitor and lasts for at least 120 seconds.

The table below lists alarm priority levels and their visual, audible, and autoreset characteristics. An alarm autoresets when the condition causing the alarm no longer exists.

Table 6-2. Alarm Prioritization

Priority Level	Visual indicator	Audible indicator	Autoreset characteristics
Immediate	Specific to alarm condition or component failure.	Continuous tone alarm sounding for at least 120 s.	N/A
High: Immediate attention required to ensure patient safety.	Flashing red omni-directional LED located on the top of the GUI, red alarm banner on GUI screen, red bar next to alarm setting icon on Alarms screen. !!!	High-priority audible alarm (a sequence of five tones that repeats twice, pauses, then repeats again).	Visual alarm does not auto reset. Visual alarm indicators remain steadily illuminated following an autoreset. The alarm reset key must be pressed to extinguish visual indicator.
Medium: Prompt attention necessary.	Flashing yellow omni-directional LED located on the top of the GUI, yellow alarm banner on GUI screen, and yellow bar next to alarm setting icon on Alarms screen. !!	Medium-priority audible alarm (a repeating sequence of three tones).	LED indicator turns off and autoreset is entered into the alarm log.
Low: A change in the patient-ventilator system has occurred.	Steadily illuminated yellow omni-directional LED located on the top of the GUI, yellow alarm banner on GUI screen, and yellow bar next to alarm setting icon on Alarms screen. !	Low-priority audible alarm (two tone, non-repeating).	LED indicator turns off and autoreset is entered into the alarm log.

Table 6-2. Alarm Prioritization (Continued)

Priority Level	Visual indicator	Audible indicator	Autoreset characteristics
Normal: Normal ventilator operation	Steadily illuminated green omni-directional LED located on the top of the GUI, no alarm banner, and white values next to alarm setting icon on Alarms screen.	None.	None
Immediate	Status display shows the GUI has failed.	The secondary alarm annunciates a repeating sequence of single tones, since the primary alarm (part of the GUI) has failed.	None

A ***technical alarm*** is one that is caused by a violation of any of the ventilator's self monitoring conditions, such as failure of POST or a fault detected by the ventilator's background diagnostic system. Technical alarms cannot be reset by pressing the Alarm Reset key. (Reference *Background Diagnostic System*, p. 10-74). Technical alarms fall into eight categories, shown in the table below.

Table 6-3. Technical Alarm Categories

Category	Name	Priority	System Response
1	Vent-Inop	High	Ventilator goes to safe state. Reference *Ventilator Protection Strategies*, p. 4-35.
2	Exh BUV	High	Backup ventilation
3	Insp BUV	High	Backup ventilation
4	Mix BUV	High	Backup ventilation
5	SVO	High	Ventilator goes to safe state. Reference *Ventilator Protection Strategies*, p. 4-35.
6	Caution	High	Ventilation continues as set
7	Warning	Medium	Ventilation continues as set
8	Notification	Low	Ventilation continues as set (not displayed on alarm banner)

Reference the table below for a list of ventilator technical alarms, their meaning, and what to do if they occur.

Reference *Alarm Settings Range and Resolution*, p. 11-17 for the settings, ranges, resolutions, new patient default values, and accuracies of all the ventilator alarms.

Table 6-4. Technical Alarms

Alarm message	Meaning	What to do
O_2 SENSOR	O_2 sensor is out of calibration or has failed.	Re-calibrate or replace O_2 sensor.
DEVICE ALERT	Various. Technical alarm category is described. Reference *Technical Alarm Categories*, p. 6-17. More information for the particular technical alarm can be found in the System diagnostic log, a link to which is provided on the expanded alarm banner.	Follow remedy message displayed on GUI.

A ***non-technical alarm*** is an alarm caused due to a fault in the patient-ventilator interaction or a fault in the electrical or gas supplies that the practitioner may be able to alleviate.

Table 6-5. Non-technical Alarm Summary

Base message	Priority	Analysis message	Remedy message	Comments
AC POWER LOSS	Low	Operating on vent main battery.	N/A	Ventilator's power switch is ON. Ventilator automatically switches to battery power. AC power not available. Battery operating indicator on status display turns on. Resets when AC power is restored.

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
APNEA (patient data alarm)	Medium	Apnea ventilation. Breath interval > apnea interval.	Check patient & settings.	The set apnea interval has elapsed without the ventilator, patient, or operator triggering a breath. Resets after patient initiates a third consecutive breath. Possible dependent alarm: $\downarrow\dot{V}_{E\ TOT}$
	High	Extended apnea duration or multiple apnea events.		
CIRCUIT DISCONNECT	High	No ventilation	Check patient Reconnect circuit.	Ventilator has recovered from unintended power loss lasting more than five minutes, detects circuit disconnect. The GUI screen displays elapsed time without ventilator support. Resets when patient is reconnected.
	High	No ventilation	Check patient. Reconnect circuit.	Ventilator detects circuit disconnect; the GUI screen displays elapsed time without ventilator support. Resets when patient is reconnected.
COMPLIANCE LIMITED V_T (alarm is not adjustable) (patient data alarm)	Low	Compliance compensation limit reached	Check patient and circuit type. Inspired volume may be < set.	Compliance volume required to compensate delivery of a VC, VC+ or VS breath exceeds the maximum allowed for 3 of the last 4 breaths.

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
↑P_{PEAK} (patient data alarm)	Low	Last breath ≥ set limit.	Check patient, circuit & ET tube.	Measured airway pressure ≥ set limit. Ventilator truncates current breath unless already in exhalation. Possible dependent alarms: ↓$V_{TE\ MAND}$, ↓ $\dot{V}_{E\ TOT}$, ↑f_{TOT}. Corrective action: Check patient. Check tube type/ID setting. Consider reducing % Supp setting or increasing ↑P_{PEAK}.
	Medium	Last 3 breaths ≥ set limit.		
	High	Last 4 or more breaths ≥ set limit.		
↑P_{COMP} (patient data alarm)	Low	Last spont breath ≥ set P_{PEAK} limit - 5 cmH_2O.	**In TC:** • Check for leaks, tube type/ID setting.	Pressure of spontaneous breaths ≥ set limit. Possible dependent alarms: ↓ $V_{TE\ SPONT}$, ↓ $\dot{V}_{E\ TOT}$, ↑f_{TOT}, ↓$V_{TE\ SPONT}$ Corrective action: Check for leaks. Check for the correct tube type. Check that the tube inside diameter corresponds to the patient PBW. Check the ↑P_{PEAK} setting.
	Medium	Last 3 spont breaths ≥ set P_{PEAK} limit - 5 cmH_2O.		
	High	Last 4 or more spont breaths ≥ set P_{PEAK} limit- 5 cmH_2O.		

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
↓P_{PEAK} (patient data alarm)	Low	Last 2 breaths, pressure ≤ set limit.	Check for leaks.	Peak inspiratory pressure ≤ alarm setting. (Available only when Mandatory Type is VC+* or when Vent Type is NIV. Target pressure = the low limit: PEEP + 3 cmH_2O. Ventilator cannot deliver target volume. Possible dependent alarms: ↑f_{TOT}. Corrective action: Check patient and settings; check for leaks.
	Medium	Last 4 breaths, pressure ≤ set limit		
	High	Last10 or more breaths, pressure ≤ set limit		
* Because the VC+ pressure control algorithm does not allow the target inspiratory pressure to fall below PEEP + 3 cmH_2O, attempting to set the ↓P_{PEAK} alarm limit at or below this level will turn the alarm off.				
↑O_2% (patient data alarm)	Medium	Measured O_2% > set for ≥ 30 s but < 2 min	Check patient, gas sources, O_2 analyzer & ventilator.	The O_2% measured during any phase of a breath cycle is 7% (12% during the first hour of operation) or more above the O_2% setting for at least 30 seconds. (These percentages increase by 5% for four minutes following a decrease in the O_2% setting.)
	High	Measured O_2% > set for ≥ 2 min.		

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
↓O_2% (patient data alarm)	High	Measured O_2% < set O_2%.	Check patient, gas sources, O_2 analyzer & ventilator.	The O_2% measured during any phase of a breath cycle is 7% (12% during the first hour of operation) or more below the O_2% setting for at least 30 seconds, or below 18%. (These percentages increase by 5% for four minutes following an increase in the O_2% setting.)
↑V_{TE} (patient data alarm	Low	Last 2 breaths ≥ set limit.	Check settings, changes in patient's R&C.	Exhaled tidal volume ≥ set limit. Alarm updated whenever exhaled tidal volume is recalculated. Possible dependent alarm: ↑$\dot{V}_{E\ TOT}$
	Medium	Last 4 breath s≥ set limit.		
	High	Last 10 or more breaths ≥ set limit.		
↑$\dot{V}_{E\ TOT}$ (patient data alarm)	Low	$\dot{V}_{E\ TOT}$ ≥ set limit for ≤ 30 s	Check patient and settings.	Expiratory minute volume ≥ set limit. Alarm updated whenever an exhaled minute volume is recalculated. Possible dependent alarm: ↑V_{TE}.
	Medium	$\dot{V}_{E\ TOT}$ ≥ set limit for > 30 s		
	High	$\dot{V}_{E\ TOT}$ ≥ set limit for > 120 s		
↑f_{TOT} (patient data alarm)	Low	f_{TOT} ≥ set limit for ≤ 30 s.	Check patient & settings.	Total respiratory rate ≥ set limit. Alarm updated at the beginning of each inspiration. Reset when measured respiratory rate falls below the alarm limit. Possible dependent alarms: ↓$V_{TE\ MAND}$, ↓$V_{TE\ SPONT}$, ↓$\dot{V}_{E\ TOT}$.
	Medium	f_{TOT} ≥ set limit for > 30 s.		
	High	f_{TOT} ≥ set limit for > 120 s.		

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
↑P_{VENT} (patient data alarm)	Low	1 breath ≥ limit.	Check patient, circuit & ET tube.	Inspiratory pressure > 100 cmH_2O and mandatory type is VC or spontaneous type is TC or PAV+. Ventilator truncates current breath unless already in exhalation. Possible dependent alarms: ↓$V_{TE\ MAND}$, ↓$\dot{V}_{E\ TOT}$, ↑f_{TOT}. Corrective action: 1. Check patient for agitation. Agitated breathing, combined with high % Supp setting in PAV+ can cause over-assistance. Consider reducing % Supp setting. 2. Provide alternate ventilation. Remove ventilator from use and contact Service.
	Medium	2 breaths ≥ limit.		
	High	3 or more breaths ≥ limit.		
INOPERATIVE BATTERY	Low	Inadequate charge or nonfunctional ventilator's primary battery.	Service/replace ventilator's primary battery.	Battery installed but not functioning or charging for ≥ 6 hours. Resets when battery is functional.

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
INSPIRATION TOO LONG (patient data alarm)	Low	Last 2 spont breaths = PBW based T_I limit.	Check patient. Check for leaks.	Inspiratory time for spontaneous breath ≥ PBW-based limit. Ventilator transitions to exhalation. Resets when T_I falls below PBW-based limit. Active only when Vent Type is INVASIVE.
	Medium	Last 4 spont breaths = PBW based T_I limit.		
	High	Last 10 or more spont breaths = PBW based T_I limit.		
PAV STARTUP TOO LONG (patient data alarm) (occurs only if PAV+ is in use)	Low	PAV startup not complete for ≥ 45 s.	Check for leaks, shallow breathing, & settings for ↑V_{TI} and ↑P_{PEAK}.	Unable to assess patient's resistance and compliance during PAV startup. Possible dependent alarms ↓$V_{TE\ SPONT}$, ↓$\dot{V}_{E\ TOT}$, ↑f_{TOT}. Corrective action: Check patient. (Patient's inspiratory times may be too short to evaluate resistance and compliance.) Check that selected humidification type and empty humidifier volume are correct.
	Medium	PAV startup not complete for ≥ 90 s.		
	High	PAV startup not complete for ≥ 120 s.		

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
PAV R & C NOT ASSESSED (patient data alarm) (occurs only if PAV+ is in use)	Low	R and/or C over 15 minutes old.	Check for leaks, shallow breathing, & settings for tube ID, ↑V_{TI} and ↑P_{PEAK}.	Unable to assess resistance and/or compliance during PAV+ steady-state. Startup was successful, but later assessments were unsuccessful. Corrective action: Check patient. (Patient's inspiratory times may be too short to evaluate resistance and compliance.) Check that selected humidification type and empty humidifier volume are correct.
	Medium	R and/or C over 30 minutes old.		
LOSS OF POWER	Immediate	N/A	N/A	The ventilator power switch is ON and there is insufficient power from AC and the battery. There may not be a visual indicator for this alarm, but an independent audio alarm sounds for at least 120 seconds. Alarm annunciation can be reset by turning power switch to OFF position.
LOW BATTERY	Medium	Operating on battery.Ventilator battery operational time < 10 minutes.	Replace or allow ventilator battery to recharge.	Resets when battery has ≥ ten minutes of operational time remaining or when AC power is restored.

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
LOW BATTERY	High	Operating on battery. Ventilator battery operational time < 5 minutes	Replace or allow ventilator battery to recharge	Resets when battery has ≥ five minutes of operational time remaining or when AC power is restored.
↓$V_{TE\ MAND}$ (patient data alarm)	Low	Last 2 mand breaths ≤ set limit.	Check for leaks, changes in patient's R & C.	Exhaled mandatory tidal volume≤ set limit. Alarm updated whenever exhaled mandatory tidal volume is recalculated. Possible dependent alarms: ↓$\dot{V}_{E\ TOT}$, ↑f_{TOT}.
	Medium	Last 4 mand breaths ≤ set limit.		
	High	Last 10 or more mand breaths ≤ set limit.		
↓$V_{TE\ SPONT}$ (patient data alarm)	Low	Last 4 spont breaths ≤ set limit	Check patient & settings.	Exhaled spontaneous tidal volume ≤ set limit. Alarm updated whenever exhaled spontaneous tidal volume is recalculated. Possible dependent alarms: ↓$\dot{V}_{E\ TOT}$, ↑f_{TOT}.
	Medium	Last 7 spont breaths ≤ set limit		
	High	Last 10 or more spont breaths ≤ set limit		

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
↑V_{TI} (patient data alarm)	Low	Last spont breath ≥ set limit.	**In TC, VS, or PAV+:** • Check patient and settings.	Delivered inspiratory volume ≥ inspiratory limit. Ventilator transitions to exhalation. Possible dependent alarms: ↓$V_{TE\ SPONT}$,↓$\dot{V}_{E\ TOT}$, ↑f_{TOT} Corrective action: Check for leaks. Check for the correct tube type. Check the V_{TI} or V_{TI} setting. In PAV+, check for patient agitation, which can cause miscalculation of R_{PAV} and C_{PAV}. Consider reducing % Supp setting. Check ↑V_{TI}.
	Medium	Last 3 spont breaths ≥ set limit.		
	High	Last 4 or more spont breaths ≥ set limit.		
↓$\dot{V}_{E\ TOT}$ (patient data alarm)	Low	$\dot{V}_{E\ TOT}$ ≤ set limit for ≤ 30 s.	Check patient & settings.	Total minute volume ≤ set limit. Alarm updated whenever exhaled minute volume is recalculated. Possible dependent alarms↓$V_{TE\ MAND}$, ↓$V_{TE\ SPONT}$, ↑f_{TOT}
	Medium	$\dot{V}_{E\ TOT}$ ≤ set limit for > 30 s.		
	High	$\dot{V}_{E\ TOT}$ ≤ set limit for > 120 s.		

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
VOLUME NOT DELIVERED (not adjustable) (patient data alarm)	Low	Last 2 spont (or mand) breaths pressure > max allowable level.	Check patient and setting for ↑P_{PEAK}.	Insp target pressure > (P_{PEAK} - PEEP - 3 cmH_2O), when spontaneous type is VS or mandatory type is VC+. Ventilator cannot deliver target volume. Possible dependent alarms: For VC+ breaths: ↓$V_{TE\ MAND}$ ↓$\dot{V}_{E\ TOT}$ ↑f_{TOT} For VS breaths: ↓$V_{TE\ SPONT}$, ↓$\dot{V}_{E\ TOT}$, ↑f_{TOT} Corrective action: Check patient and settings.
	Medium	Last 10 or more spont (or mand) breaths, pressure > max allowable level.		
NO AIR SUPPLY	High	Ventilation continues as set except O_2= 100%	Check patient and air source	Switch to 100% O_2.
NO O_2 SUPPLY	Low	Ventilation continues as set. Only air available.	Check O_2 source.	Operator-set O_2% equals 21%. Resets if O_2 supply connected
	High	Ventilation continues as set, except O_2% = 21.	Check patient & O_2 source.	Ventilator delivers 21% O_2 instead of set O_2%. Resets if oxygen supply connected.
PROCEDURE ERROR	High	Patient connected before setup complete	Provide alternate ventilation. Complete setup process.	Ventilator begins safety ventilation. Resets when ventilator startup procedure is complete.

Table 6-5. Non-technical Alarm Summary (Continued)

Base message	Priority	Analysis message	Remedy message	Comments
SEVERE OCCLUSION	High	Little/no ventilation.	Check patient. Provide alternate ventilation. Clear occlusions; drain circuit.	Ventilator enters occlusion status cycling (OSC). Patient data displays are blanked and GUI screen displays elapsed time without ventilator support.
PROX INOPERATIVE (if Proximal Flow Sensor is in use)	Low	Data from Proximal Flow Sensor are not being used.	Check proximal flow sensor connections and tubes for occlusions or leaks	Data obtained from the proximal flow sensor are invalid, non-existent, or unreasonable based on current ventilator settings or purge lines are occluded. Alarm resets when condition is corrected. Data for real time waveforms and monitored volumes are obtained from internal sensors.
INADVERTENT POWER OFF	High	Ventilator switched OFF with patient connected to breathing circuit.	Return power switch to ON position and disconnect patient before turning power off.	User must acknowledge turning the power OFF by touching *Power Off* on the GUI.

Table 6-6. Non-Technical Alarms and Suggested Responses

Alarm message	Meaning	Response
AC POWER LOSS	The ventilator is running on battery power.	Monitor the battery charge level to ensure there is enough power remaining to operate the ventilator.
APNEA (patient data alarm)	The time between patient breaths exceeds the set apnea interval.	Check patient and settings.

Table 6-6. Non-Technical Alarms and Suggested Responses (Continued)

Alarm message	Meaning	Response
CIRCUIT DISCONNECT	The patient circuit has become disconnected or there is a large leak in the patient circuit.	Re-connect the patient circuit, or eliminate the leak.
Compliance limited V_T (patient data alarm)	Compliance volume required to compensate delivery of a VC, VC+, or VS breath exceeds the maximum allowed for three of the last four breaths.	Check patient and circuit type. Inspired volume may be less than set.
↑P_{PEAK} (patient data alarm)	The measured airway pressure is ≥ set limit. Reduced tidal volume likely.	• Check the patient • Check the patient circuit • Check the endotracheal tube
↓P_{PEAK} (patient data alarm)	The peak inspiratory pressure in the patient circuit ≤ alarm setting.This alarm is only available when NIV is the selected Vent Type or when VC+ is the selected Mandatory type during INVASIVE ventilation.*	Check for leaks in the patient circuit and VBS.
* Because the VC+ pressure control algorithm does not allow the target inspiratory pressure to fall below PEEP + 3 cmH_2O, attempting to set the ↓P_{PEAK} alarm setting at or below this level will turn the alarm off.		
↑O_2% (patient data alarm)	The O_2% measured during any phase of a breath cycle is 7% (12% during the first hour of operation) or more above the O_2% parameter for at least 30 seconds.The percentage window increases by 5% for four minutes after increasing the set O_2% value.	Check the patient, the air and oxygen supplies, the oxygen analyzer, and the ventilator.

Table 6-6. Non-Technical Alarms and Suggested Responses (Continued)

Alarm message	Meaning	Response
↓O_2% (patient data alarm)	The O_2% measured during any phase of a breath cycle is 7% (12% during the first hour of operation) or more below the O_2% parameter for at least 30 seconds. The percentage window increases by 5% for four minutes after increasing the set O_2% value.	• Check the patient, the air and oxygen supplies, the oxygen analyzer, and the ventilator. • Calibrate oxygen sensor. Reference *Oxygen Sensor Calibration*, p. 4-34 for details regarding calibrating the oxygen sensor. • Use an external O_2 monitor and disable the O_2 sensor.
↑V_{TE} (patient data alarm)	Exhaled tidal volume ≥ alarm setting for the last two breaths.	• Check patient settings • Check for changes in patient's resistance and compliance.
↑$\dot{V}_{E\ TOT}$ (patient data alarm)	Minute volume ≥ alarm setting.	Check patient settings.
↑f_{TOT} (patient data alarm)	The breath rate from all breaths is ≥ alarm setting.	Check the patient and the ventilator settings.
↑P_{VENT} (patient data alarm)	The inspiratory pressure transducer has measured a pressure > 110 cmH_2O in VC, TC, or PAV+. The ventilator transitions to exhalation. A reduced tidal volume is likely.	• Check the patient, the patient circuit (including filters), and the endotracheal tube. Ensure the ET tube ID is the correct size. Check the ventilator flow and/or volume settings. • Re-run SST. • Obtain an alternate ventilation source. • Remove the ventilator from clinical use and obtain service.
INOPERATIVE BATTERY	The battery charge is inadequate after 6 hours of attempted charge time or the battery system is non-functional.	Replace the battery or install an extended battery.

Table 6-6. Non-Technical Alarms and Suggested Responses (Continued)

Alarm message	Meaning	Response
INSPIRATION TOO LONG (patient data alarm)	The PBW-based inspiratory time for the last two spontaneous breath exceeds the ventilator-set limit. Active only when Vent Type is INVASIVE.	• Check the patient. • Check the patient circuit for leaks. • Check Rise time % and E_{SENS} settings.
LOSS OF POWER	The ventilator power switch is ON, but there is insufficient power from the mains AC and the battery. There may not be a visual indicator for this alarm, but an independent audio alarm (immediate priority) sounds for at least 120 seconds.	• Check the integrity of the AC power and battery connections. • Obtain alternative ventilation if necessary. • Install an extended battery If the loss of power event has been resolved, turn the power switch OFF and back ON again to reset the alarm.
LOW BATTERY	Medium priority alarm indicating < ten (10) minutes of battery power remaining to operate the ventilator. High priority alarm indicating < five (5) minutes of battery power remain to operate the ventilator.	Recharge the battery, by plugging the ventilator into AC power or replace the battery, or install an extended battery.
$\downarrow V_{TE\ MAND}$ (patient data alarm)	The patient's exhaled mandatory tidal volume is ≤ alarm setting for the last two mandatory breaths.	• Check the patient. • Check for leaks in the patient circuit. • Check for changes in the patient's resistance or compliance.
$\downarrow V_{TE\ SPONT}$ (patient data alarm)	The patient's exhaled spontaneous tidal volume is ≤ alarm setting for the last two spontaneous breaths.	• Check the patient. • Check the ventilator settings.

Table 6-6. Non-Technical Alarms and Suggested Responses (Continued)

Alarm message	Meaning	Response
$\downarrow\dot{V}_{E\ TOT}$ (patient data alarm)	The minute volume for all breaths is ≤ alarm setting.	• Check the patient. • Check the ventilator settings.
NO AIR SUPPLY	The air supply pressure is less than the minimum pressure required for correct ventilator operation. The ventilator delivers 100% O_2 if available. If an oxygen supply is not available, the safety valve opens. The ventilator displays the elapsed time without ventilator support. This alarm cannot be set or disabled.	• Check the patient. • Check the air and oxygen sources. • Obtain alternative ventilation if necessary.
NO O_2 SUPPLY	The oxygen supply pressure is less than the minimum pressure required for correct ventilator operation. The ventilator delivers 100% air if available. If an air supply is not available, the safety valve opens. The ventilator displays the elapsed time without ventilatory support. This alarm cannot be set or disabled.	• Check the patient. • Check the air and oxygen sources. • Obtain alternative ventilation if necessary.
$\uparrow P_{COMP}$	Target pressure ≥ ($\bar{\uparrow}P_{PEAK}$ - 5 cmH_2O	**In TC:** • Check for leaks and tube type/I.D. setting **In PAV+:** • Limit target pressure to $\bar{\uparrow}P_{PEAK}$ - 5 cmH_2O
PROCEDURE ERROR	The patient is attached before ventilator startup is complete. Safety ventilation is active.	• Provide alternate ventilation if necessary. • Complete ventilator startup procedure.

Table 6-6. Non-Technical Alarms and Suggested Responses (Continued)

Alarm message	Meaning	Response
SEVERE OCCLUSION	The patient circuit is severely occluded. The ventilator enters occlusion status cycling. The elapsed time without ventilatory support appears.	• Check the patient. • Obtain alternative ventilation if necessary. • Check patient circuit for bulk liquid, crimps, blocked filter. • If problem persists, remove ventilator from use and obtain service.
$\uparrow V_{TI}$ (patient data alarm)	Delivered inspiratory volume ≥ high inspiratory volume limit	Ventilator transitions to exhalation. • Check for leaks and tube type/ID setting. • Check patient and ventilatorsettings. • Check for leaks, tube type/ID and% $_{Supp}$ settings, and patient agitation.
VOLUME NOT DELIVERED (patient data alarm	Insp target pressure > (P_{PEAK} - PEEP - 3 cmH_2O), when spontaneous type is VS or when mandatory type is VC+.	Check patient and $\uparrow P_{PEAK}$ setting
PAV STARTUP TOO LONG (occurs only if PAV+ option is in use)	Unable to assess resistance and/or compliance during PAV+ startup.	Check for leaks, shallow breathing, and settings for $\uparrow V_{TI}$ and $\uparrow P_{PEAK}$
PAV R & C NOT ASSESSED (occurs only if PAV+ option is in use)	Unable to assess resistance and/or compliance during PAV+ steady-state.	Check for leaks, shallow breathing, and settings for tube ID, $\uparrow V_{TI}$ and $\uparrow P_{PEAK}$.
PROX INOPERATIVE	A malfunction occurred with the Proximal Flow Sensor or the pneumatic lines are occluded.	Replace the Proximal Flow Sensor or purge its pneumatic lines. Does not affect data from the ventilator's delivery or exhalation valve flow sensors.

The next sections provide detailed descriptions of selected alarms.

6.5.9 AC POWER LOSS Alarm

The AC POWER LOSS alarm indicates the ventilator power switch is on and the ventilator is being powered by the battery and an alternate power source may soon be required to sustain normal ventilator operation. The ventilator annunciates a medium-priority LOW BATTERY alarm when the ventilator has less than ten minutes of battery power remaining. The ventilator annunciates a high-priority LOW BATTERY alarm when less than five minutes of battery power are estimated available.

6.5.10 Apnea Alarm

The APNEA alarm indicates neither the ventilator nor the patient has triggered a breath for the operator-selected apnea interval (T_A). T_A is measured from the start of an inspiration to the start of the next inspiration and is based on the ventilator's inspiratory detection criteria. T_A can only be set via the apnea ventilation settings.

The APNEA alarm autoresets after the patient initiates two successive breaths, and is intended to establish the patient's inspiratory drive is reliable enough to resume normal ventilation. To ensure the breaths are patient-initiated (and not due to autotriggering), exhaled volumes must be at least half the inspired V_T (this avoids returning to normal ventilation if there is a disconnect).

6.5.11 CIRCUIT DISCONNECT Alarm

The CIRCUIT DISCONNECT alarm indicates the patient circuit is disconnected at the ventilator or the patient side of the patient wye, or a large leak is present. The methods by which circuit disconnects are detected vary depending on breath type. Time, pressure, flow, delivered volume, exhaled volume, and the D_{SENS} setting may be used in the circuit disconnect detection algorithms. Reference *Disconnect*, p. 10-47 for a complete discussion of the CIRCUIT DISCONNECT detection methods.

The CIRCUIT DISCONNECT alarm sensitivity is adjusted via the D_{SENS} setting. During a CIRCUIT DISCONNECT condition, the ventilator enters an idle state and delivers a base flow of oxygen to detect a reconnection.

When the ventilator determines the patient circuit is reconnected, the CIRCUIT DISCONNECT alarm autoresets and normal ventilation resumes without having to manually reset the alarm (for example, following suctioning).

A disconnected patient circuit interrupts gas delivery and patient monitoring. Notification of a patient circuit disconnect is crucial, particularly when the patient cannot breathe spontaneously. The ventilator does not enter apnea ventilation when a disconnect is detected to avoid changing modes during a routine suctioning procedure.

Note:
When utilizing a closed-suction catheter system, the suctioning procedure can be executed using existing mode, breath type and settings. To reduce potential for hypoxemia during the procedure, elevate the oxygen concentration using the Elevate O_2 control. Reference *To adjust the amount of elevated O_2 delivered for two minutes*, p. 3-40.

6.5.12 Loss of Power Alarm

This alarm alerts the operator that there is insufficient battery power and no AC power to support ventilator operation. The alarm annunciates as long as the ventilator's power switch is in the ON position, and lasts for at least 120 seconds.

6.5.13 DEVICE ALERT Alarm

A DEVICE ALERT alarm indicates a background test or Power On Self Test (POST) has failed. Depending on which test failed, the ventilator either continues to ventilate according to current settings, or ventilates with modified settings, or enters the ventilator inoperative state. The DEVICE ALERT alarm relies on the ventilator's self-testing and notifies the clinician of an abnormal condition requiring service. Reference *Background Diagnostic System*, p. 10-74.

6.5.14 High Circuit Pressure (↑P_{PEAK}) Alarm

The ↑P_{PEAK} alarm indicates the currently measured airway pressure is equal to or greater than the set limit. The ↑P_{PEAK} limit is active during all breath types and phases to provide redundant patient protection (for example, to detect air flow restrictions downstream of the pressure-sensing device). The ↑P_{PEAK} limit is active in all normal ventilation modes. The ↑ P_{PEAK} alarm new patient default values are separately configurable for neonatal, pediatric, and adult patients. The↑P_{PEAK} limit is not active during a SEVERE OCCLUSION alarm.

The ↑P_{PEAK} alarm truncates inspiration and transitions the ventilator into the exhalation phase and the limit cannot be set less than

- PEEP + 7 cmH_2O, or
- PEEP + P_I + 2 cmH_2O, or
- PEEP + P_{SUPP} + 2 cmH_2O

nor can it be set less than or equal to ↓P_{PEAK}.

The ↑P_{PEAK} limit cannot be disabled. The ventilator phases in changes to the ↑P_{PEAK} limit immediately to allow prompt notification of a high circuit pressure condition.

The minimum ↑P_{PEAK} limit (7 cmH_2O) corresponds to the lowest peak pressures not due to autotriggering anticipated during a mandatory breath. The maximum ↑P_{PEAK} limit (100 cmH_2O) was selected because it is the maximum pressure required to inflate very low-compliance lungs.

The ventilator allows circuit pressure to rise according to a computed triggering profile for the initial phase of PC and PS breaths without activating the ↑P_{PEAK} alarm. This triggering profile helps avoid nuisance alarms due to possible transient pressure overshoot in the airway when aggressive values of rise time % are selected. A brief pressure overshoot measured in the patient circuit is unlikely to be present at the carina.

6.5.15 High Delivered O_2% (↑O_2%) Alarm

The ↑O_2% alarm indicates the measured O_2% is at or above the error percentage above the O_2% setting for at least 30 seconds to eliminate transient O_2% delivery variation nuisance alarms. The ↑O_2% alarm detects malfunctions in ventilator gas delivery or oxygen monitor. The ventilator declares a ↑O_2% alarm after 30 seconds. Although the ventilator automatically sets the ↑O_2% alarm limits, the oxygen sensor can be disabled. (The error percentage is 12% above setting for the first hour of ventilator operation, 7% above the setting after the first hour of operation, and an additional 5% above the setting for the first four minutes following a decrease in the setting.)

The ventilator automatically adjusts the ↑O_2% alarm limit when O_2% changes due to 100% O_2, apnea ventilation, occlusion, circuit disconnect, or a NO AIR/

O_2 SUPPLY alarm. The ventilator checks the ↑O_2% alarm limit against the measured oxygen percentage at one-second intervals.

6.5.16 High Exhaled Minute Volume (↑$\dot{v}_{E\ TOT}$) Alarm

The ↑$\dot{v}_{E\ TOT}$ alarm indicates the measured exhaled total minute volume for spontaneous and mandatory breaths is equal to or greater than the alarm setting. The ↑$\dot{v}_{E\ TOT}$ alarm is effective immediately upon changing the setting, to ensure prompt notification of prolonged high tidal volumes.

The ↑$\dot{v}_{E\ TOT}$ alarm can be used to detect a change in a patient's breathing pattern, or a change in compliance or resistance. The ↑$\dot{v}_{E\ TOT}$ alarm can also detect too-large tidal volumes, which could lead to hyperventilation and hypocarbia.

6.5.17 High Exhaled Tidal Volume (↑V_{TE}) Alarm

The ↑V_{TE} alarm indicates the measured exhaled tidal volume for spontaneous and mandatory breaths is equal to or greater than the set ↑V_{TE} alarm. The ↑V_{TE} alarm is updated whenever a new measured value is available.

The ↑V_{TE} alarm can detect increased exhaled tidal volume (due to greater compliance and lower resistance) and prevent hyperventilation during pressure control ventilation or pressure support. Turn the ↑V_{TE} alarm OFF to avoid nuisance alarms. (Hyperventilation due to increased compliance is not a concern during volume-based ventilation, because the tidal volume is fixed by the clinician's choice and the ventilator’s compliance-compensation algorithm.)

6.5.18 High Inspired Tidal Volume (↑V_{TI}) Alarm

The high inspired tidal volume alarm indicates the patient’s inspired volume exceeds the set limit. When this condition occurs, the breath terminates and the alarm sounds. The ventilator displays monitored inspired tidal volume values in the patient data area on the GUI screen. When Vent Type is NIV, there is no high inspired tidal volume alarm or setting available, but the monitored inspired tidal volume (V_{TI}) may appear in the patient data area on the GUI screen.

6.5.19 High Respiratory Rate ↑(f_{TOT}) Alarm

The ↑f_{TOT} alarm indicates the measured breath rate is greater than or equal to the $\overline{\uparrow} f_{TOT}$ alarm setting. The ↑f_{TOT} alarm is updated whenever a new total measured respiratory rate is available.

The ↑f_{TOT} alarm can detect tachypnea, which could indicate the tidal volume is too low or the patient's work of breathing has increased. The ventilator phases in changes to the $\overline{\uparrow} f_{TOT}$ limit immediately to ensure prompt notification of a high respiratory rate condition.

6.5.20 INSPIRATION TOO LONG Alarm

The INSPIRATION TOO LONG alarm, active only when Vent Type is INVASIVE, indicates the inspiratory time of a spontaneous breath exceeds the following time limit

(1.99 + 0.02 x PBW) seconds (adult and pediatric circuits)

(1.00 + 0.10 x PBW) seconds (neonatal circuits)

where PBW is the current setting for predicted body weight in kg.

When the ventilator declares an INSPIRATION TOO LONG alarm, the ventilator terminates inspiration and transitions to exhalation. The INSPIRATION TOO LONG alarm applies only to spontaneous breaths and cannot be set or disabled.

Because leaks (in the patient circuit, around the endotracheal tube cuff, or through chest tubes) and patient-ventilator mismatch can affect accurate exhalation detection, the INSPIRATION TOO LONG alarm can act as a backup method of safely terminating inspiration. If the INSPIRATION TOO LONG alarm occurs frequently, check for leaks and ensure E_{SENS} and rise time % are properly set.

6.5.21 Low Circuit Pressure (↓P_{PEAK}) Alarm

The ↓P_{PEAK} alarm indicates the measured maximum airway pressure during the current breath is less than or equal to the set alarm level during a non-invasive inspiration or during a VC+ inspiration.

The $\downarrow P_{PEAK}$ alarm is active for mandatory and spontaneous breaths, and is present only when Vent Type is NIV or Mandatory Type is VC+. During VC+, the $\downarrow P_{PEAK}$ alarm can be turned OFF. The $\downarrow P_{PEAK}$ alarm can always be turned OFF during NIV. The $\downarrow P_{PEAK}$ alarm limit cannot be set to a value greater than or equal to the $\uparrow P_{PEAK}$ alarm limit.

WARNING:
Because the VC+ pressure control algorithm does not allow the target inspiratory pressure to fall below PEEP + 3 cmH_2O, attempting to set the $\downarrow P_{PEAK}$ alarm limit at or below this level will turn the alarm off.

In VC+, whenever PEEP is changed, $\downarrow P_{PEAK}$ is set automatically to its New Patient value, PEEP + 4 cmH_2O when PEEP ≥ 16 cmH_2O, or PEEP + 3.5 cmH_2O when PEEP < 16 cmH_2O.

There are no alarms dependent upon $\downarrow P_{PEAK}$, and the $\downarrow P_{PEAK}$ alarm does not depend on other alarms.

6.5.22 Low Delivered O_2% ($\downarrow O_2$%) Alarm

The $\downarrow O_2$% alarm indicates the measured O_2% during any phase of a breath is at or below the error percentage below the O_2% setting, or less than or equal to 18%, for at least 30 seconds. Although the ventilator automatically sets the $\downarrow O_2$% alarm, replace (if necessary) or disable the oxygen sensor to avoid nuisance alarms. (The error percentage is 12% below setting for the first hour of ventilator operation following a reset, 7% below setting after the first hour of operation, and an additional 5% below setting for the first four minutes following an increase in the setting.)

The ventilator automatically adjusts the $\downarrow O_2$% alarm limit when O_2% changes due to apnea ventilation, circuit disconnect, or a NO O_2/AIR SUPPLY alarm. The $\downarrow O_2$% alarm is disabled during a safety valve open (SVO) condition. The ventilator checks the $\downarrow O_2$% alarm against the measured oxygen percentage at one-second intervals.

The $\downarrow O_2$% alarm can detect malfunctions in ventilator gas delivery or the oxygen monitor, and can ensure the patient is adequately oxygenated. The ventilator declares a $\downarrow O_2$% alarm after 30 seconds to eliminate nuisance alarms from transient O_2% delivery variations. The O_2% measured by the

oxygen sensor is shown in the patient data area. Reference *Vital Patient Data*, p. 3-42 to include O_2% if it is not displayed.

6.5.23 Low Exhaled Mandatory Tidal Volume ($\downarrow V_{TE\ MAND}$) Alarm

The alarm indicates the measured exhaled mandatory tidal volume is less than or equal to the $\downarrow V_{TE\ MAND}$ alarm setting. The $\downarrow V_{TE\ MAND}$ alarm updates when a new measured value of exhaled mandatory tidal volume is available.

The $\downarrow V_{TE\ MAND}$ alarm can detect an obstruction, a leak during volume ventilation, or a change in compliance or resistance during pressure-based ventilation (that is, when the same pressure is achieved but tidal volume decreases). There are separate alarms for mandatory and spontaneous exhaled tidal volumes for use during SIMV, SPONT, and BiLevel. The ventilator phases in a change to the $\downarrow V_{TE\ MAND}$ alarm immediately to ensure prompt notification of a low exhaled tidal volume condition.

6.5.24 Low Exhaled Spontaneous Tidal Volume ($\downarrow V_{TE\ SPONT}$) Alarm

The $\downarrow V_{TE\ SPONT}$ alarm indicates the measured exhaled spontaneous tidal volume is less than or equal to the $\downarrow V_{TE\ SPONT}$ alarm setting. The alarm updates when a new measured value of exhaled spontaneous tidal volume is available.

The $\downarrow V_{TE\ SPONT}$ alarm can detect a leak in the patient circuit or a change in the patient's respiratory drive during a single breath. The $\downarrow V_{TE\ SPONT}$ alarm is based on the current breath rather than on an average to detect changes as quickly as possible. There are separate alarms for mandatory and spontaneous exhaled tidal volumes for use during SIMV and BiLevel (if this software option is installed). The ventilator phases in a change to the $\downarrow V_{TE\ SPONT}$ alarm limit immediately to ensure prompt notification of a low exhaled tidal volume condition.

6.5.25 Low Exhaled Total Minute Volume ($\downarrow \dot{v}_{E\ TOT}$) Alarm

The $\downarrow \dot{v}_{E\ TOT}$ alarm indicates the measured minute volume (for mandatory and spontaneous breaths) is less than or equal to the $\downarrow \dot{v}_{E\ TOT}$ alarm setting. The $\downarrow \dot{v}_{E\ TOT}$ alarm updates with each new calculation for exhaled minute volume.

The $\downarrow\dot{V}_{E\ TOT}$ alarm can detect a leak or obstruction in the patient circuit, a change in compliance or resistance, or a change in the patient's breathing pattern. The $\downarrow\dot{V}_{E\ TOT}$ alarm can also detect too-small tidal volumes, which could lead to hypoventilation and hypoxia (oxygen desaturation).

The ventilator phases in changes to the $\downarrow\dot{V}_{E\ TOT}$ alarm limit immediately to ensure prompt notification of prolonged low tidal volumes.

6.5.26 PROCEDURE ERROR Alarm

The ventilator declares a PROCEDURE ERROR alarm if it is powered up (either by turning on the power switch or if power is regained following a power loss of at least five minutes) and the ventilator detects a patient attached before Ventilator Startup is complete. Until confirmation of the ventilator settings, the ventilator annunciates a high-priority alarm and enters Safety PCV. Reference *Safety PCV Settings*, p. 10-72.

The PROCEDURE ERROR alarm requires confirmation of ventilator settings after restoration of ventilator power, in case a new patient is attached to the ventilator. Safety PCV is an emergency mode of ventilation providing ventilation according to displayed settings until settings confirmation, and is not intended for long-term patient ventilation.

6.5.27 Severe Occlusion Alarm

A severe occlusion alarm occurs when gas flow in the ventilator breathing system is severely restricted. The ventilator enters Occlusion Status Cycling (OSC) where the ventilator periodically attempts to deliver a pressure-based breath while monitoring inspiration and exhalation breath phases for a severe occlusion. If an occlusion is not detected, the ventilator considers the occlusion condition reset, clears the occlusion alarm, and continues ventilation with the settings in use before the occlusion occurred. The ventilator indicates an occlusion was detected.

6.6 Monitored Patient Data

Monitored patient data appear in the Patient Data Banner at the top of the GUI screen above the waveforms display. Reference *Areas of the GUI*, p. 4-3.

Reference *Vital Patient Data*, p. 3-42 to change the displayed patient data parameters or the order in which they are displayed.

If any patient data values are displayed continuously blinking, it means their values are shown clipped to what has been defined as their absolute limits. If the values are displayed in parentheses "( )", it means they are clipped to their variable limits.Variable limits are calculated values derived from the set PBW and ventilator settings. Displayed patient data values that have been clipped should be viewed as suspect.

Dashes (--) are displayed if the patient data value is not applicable based on mode/breath type combinations.

Note:
If no value is displayed, then the ventilator is in a state where the value cannot be measured.

The following sections contain descriptions of all patient data parameters shown in the patient data displays.

Note:
All displayed patient volume data represent lung volumes expressed under BTPS conditions.

6.6.1 Total Exhaled Minute Volume ($\dot{V}_{E\ TOT}$)

The BTPS and compliance compensated sum of exhaled gas volumes from both mandatory and spontaneous breaths for the previous one-minute interval.

6.6.2 Exhaled Spontaneous Minute Volume ($\dot{V}_{E\ SPONT}$)

The BTPS- and compliance-compensated sum of exhaled spontaneous volumes for the previous minute.

6.6.3 Exhaled Tidal Volume (V_{TE})

The volume of the patient's exhaled gas for the previous mandatory or spontaneous breath. Displayed V_{TE} is both compliance-and BTPS compensated, and updates at the next inspiration.

6.6.4 Proximal Exhaled Minute Volume ($\dot{V}_{E\ TOTY}$)

The BTPS- and compliance-compensated sum of exhaled spontaneous volumes for the previous minute.

6.6.5 Proximal Exhaled Tidal Volume (V_{TEY})

The exhaled tidal volume for the previous breath measured by the Proximal Flow Sensor (for neonatal patients, only). V_{TEY} is updated at the beginning of the next inspiration.

6.6.6 Exhaled Spontaneous Tidal Volume ($V_{TE\ SPONT}$)

The exhaled volume of the last spontaneous breath, updated at the beginning of the next inspiration following a spontaneous breath.

6.6.7 Exhaled Mandatory Tidal Volume ($V_{TE\ MAND}$)

The exhaled volume of the last mandatory breath, updated at the beginning of the next inspiration following a mandatory breath. If the mode is SPONT and the ventilator has not delivered mandatory breaths in a time period of greater than two minutes (for example via a manual inspiration), the $V_{TE\ MAND}$ patient data indicator becomes hidden.The indicator reappears when the value updates.

6.6.8 Exhaled mL/kg Volume

The patient's exhaled volume displayed in mL/kg PBW.

6.6.9 Inspired Tidal Volume (V_{TI})

The BTPS- and compliance-compensated volume of inspired gas for all pressure-based or NIV breaths, updated at the beginning of the following expiratory phase. V_{TI} is displayed when data are available.

6.6.10 Proximal Inspired Tidal Volume (V_{TIY})

The inspired tidal volume for a mandatory or spontaneous breath measured by the Proximal Flow Sensor (for neonatal patients, only). V_{TIY} is updated at the beginning of the following expiratory phase and is displayed when data are available.

6.6.11 Delivered mL/kg Volume

The delivered gas volume in mL/kg PBW.

6.6.12 I:E Ratio

The ratio of inspiratory time to expiratory time for the previous breath, regardless of breath type. Updated at the beginning of the next inspiration. When I:E ratio is ≥ 1:1, it is displayed as XX:1. Otherwise it is displayed as 1:XX.

Note:
Due to limitations in setting the I:E ratio in PC ventilation, the monitored data display may not exactly match the I:E ratio setting.

6.6.13 Mean Circuit Pressure (P_{MEAN})

The average circuit pressure for a complete breath period, including both inspiratory and expiratory phases whether mandatory or spontaneous. The displayed value can be either positive or negative.

6.6.14 Peak Circuit Pressure (P_{PEAK})

The maximum circuit pressure at the patient wye during the previous breath, including both inspiratory and expiratory phases.

6.6.15 End Inspiratory Pressure ($P_{I\ END}$)

The pressure at the end of the inspiratory phase of the current breath.

6.6.16 End Expiratory Pressure (PEEP)

The pressure at the end of the expiratory phase of the previous breath, updated at the beginning of the next inspiration. During an expiratory pause, the displayed value includes any active lung PEEP.

6.6.17 Intrinsic PEEP ($PEEP_I$)

$PEEP_I$ is an estimate of the pressure above the PEEP level at the end of an exhalation. $PEEP_I$ is determined during an Expiratory Pause maneuver.

6.6.18 PAV-based Intrinsic PEEP ($PEEP_{I\ PAV}$)

$PEEP_I$ is an estimate of intrinsic PEEP, updated at the end of a spontaneous PAV+ breath.

6.6.19 Total PEEP ($PEEP_{TOT}$)

$PEEP_{TOT}$ is the estimated pressure at the circuit wye during the Expiratory Pause maneuver.

6.6.20 Plateau Pressure (P_{PL})

P_{PL} is the pressure measured and displayed during an Inspiratory Pause maneuver.

6.6.21 Total Respiratory Rate (f_{TOT})

The total number of mandatory and spontaneous breaths per minute delivered to the patient.

6.6.22 PAV-based Lung Compliance (C_{PAV})

For a PAV+ breath, C_{PAV} is the change in pulmonary volume for an applied change in patient airway pressure, measured under zero-flow conditions and

updated upon successful completion of each calculation. C_{PAV} is displayed on the waveform screen.

6.6.23 PAV-based Patient Resistance (R_{PAV})

For a PAV+ breath, R_{PAV} is the change in pulmonary pressure for an applied change in patient lung flow and updated upon successful completion of each calculation. R_{PAV} is displayed on the waveform screen.

6.6.24 PAV-based Lung Elastance (E_{PAV})

For a PAV+ breath, E_{PAV} is the inverse of C_{PAV} and is updated upon successful completion of each calculation.

6.6.25 Spontaneous Rapid Shallow Breathing Index (f/ V_T)

An indication of the patient's ability to breathe spontaneously. High values generally mean the patient is breathing rapidly, but with low tidal volumes. Low values generally indicate the inverse.

6.6.26 Spontaneous Inspiratory Time Ratio (T_I/T_{TOT})

In SPONT mode, the percentage of a spontaneous breath consumed by the inspiratory phase. Updated at the successful completion of a spontaneous breath.

6.6.27 Spontaneous Inspiratory Time ($T_{I\ SPONT}$)

The duration of the inspiratory phase of a spontaneous breath and updated at the end of each spontaneous breath. $T_{I\ SPONT}$ is only calculated when the breathing mode allows spontaneous breaths and the breaths are patient-initiated.

6.6.28 PAV-based Total Airway Resistance (R_{TOT})

For a PAV+ breath, R_{TOT} is the change in pulmonary pressure for an applied change in total airway flow and updated upon the successful completion of

each calculation. If the R_{PAV} value appears in parentheses as described at the beginning of this section, the R_{TOT} value also appears in parentheses.

6.6.29 Static Compliance (C_{STAT}) and Static Resistance (R_{STAT})

C_{STAT} is an estimate of the elasticity of the patient's lungs, expressed in mL/cmH_2O. It is computed during a mandatory breath.

R_{STAT} is the total inspiratory resistance across the artificial airway and respiratory system, displayed at the start of the next inspiration after the Inspiratory Pause maneuver. It is an estimate of how restrictive the patient's airway is, based on the pressure drop at a given flow, expressed in cmH_2O/L/s. R_{STAT} is computed during a VC mandatory breath with a square flow waveform.

C_{STAT} is calculated using this equation:

$$C_{STAT} = \frac{V_{pt}}{P_{ckt} - PEEP} - C_{ckt}$$

C_{STAT}	Static compliance	P_{ckt}	The pressure in the patient circuit measured at the end of the 100 ms interval defining the pause-mechanics plateau
V_{pt}	Total expiratory volume (patient and breathing circuit)	PEEP	The pressure in the patient circuit measured at the end of expiration
C_{ckt}	Compliance of the breathing circuit during the pause maneuver (derived from SST)		

R_{STAT} is calculated using this equation after C_{STAT} is computed and assuming a VC breath type with a SQUARE waveform:

R_{STAT}	Static resistance	C_{STAT}	Static compliance

$$R_{STAT} = \frac{\left[1 + \frac{C_{ckt}}{C_{STAT}}\right]\langle P_{PEAK} - P_{PL}\rangle}{\dot{V}_{pt}}$$

C_{ckt}	Compliance of the breathing circuit during the pause maneuver (derived from SST)	P_{PL}	Mean pressure in the patient circuit over the 100 ms interval defining the pause-mechanics plateau
$\dot{V}_{pt}$	Flow into the patient during the last 100 ms of the waveform	P_{PEAK}	Peak circuit pressure

During the pause, the most recently selected graphics are displayed and frozen, to determine when inspiratory pressure stabilizes. C_{STAT} and R_{STAT} are displayed at the start of the next inspiration following the inspiratory pause and take this format:

C_{STAT} xxx

or

R_{STAT} yyy

Special formatting is applied if the software determines variables in the equations or the resulting C_{STAT} or R_{STAT} values are out of bounds:

- Parentheses ( ) signify questionable C_{STAT} or R_{STAT} values, derived from questionable variables.
- Flashing C_{STAT} or R_{STAT} values are out of bounds.
- R_{STAT} ------ means resistance could not be computed, because the breath was not of a mandatory, VC type with square flow waveform.

6.6.30 Dynamic Compliance (C_{DYN})

C_{DYN} is a dynamic estimate of static compliance for each mandatory breath delivered.

6.6.31 Dynamic Resistance (R_{DYN})

R_{DYN} is a dynamic estimate of static resistance for each mandatory breath delivered.

6.6.32 C_{20}/C

C_{20}/C is the ratio of compliance of the last 20% of inspiration to the compliance of the entire inspiration.

6.6.33 End Expiratory Flow (EEF)

A measurement of the end expiratory flow for an applicable breath.

6.6.34 Peak Spontaneous Flow (PSF)

A measurement of the maximum inspiratory spontaneous flow for an applicable spontaneous breath

6.6.35 Displayed O_2%

The percentage of oxygen in the gas delivered to the patient, measured at the ventilator's outlet, upstream of the inspiratory filter. It is intended to provide a check against the set O_2% for alarm determination, and not as a measurement of oxygen delivered to the patient. O_2% data can be displayed as long as the O_2 monitor is enabled. If the monitor is disabled, dashes (--) are displayed. If a device alert occurs related to the O_2 monitor, a blinking 0 is displayed.

7 Preventive Maintenance

7.1 Overview

This chapter contains information on maintenance of the Puritan Bennett™ 980 Series Ventilator. It includes

- How to perform routine preventive maintenance procedures, including frequency
- How to clean, disinfect, or sterilize the ventilator and its main components
- How to store the ventilator for extended periods
- How to dispose of used parts

7.2 Ventilator Operational Time

The ventilator contains an hour meter that records the number of operational hours since the ventilator was manufactured. An additional timer tracks the number of hours since the last preventive maintenance activity was performed. Both the GUI and the status display show the number of hours before the next preventive maintenance is due.

7.3 Preventive Maintenance Intervals

WARNING:
To ensure proper ventilator operation, perform Preventive Maintenance intervals as specified in the following tables. Reference *Operator Preventive Maintenance Frequency*, p. 7-2 and Reference *Service Preventive Maintenance Frequency*, p. 1-2 in the Operator's Manual Addendum on Preventive Maintenance.

Table 7-1. Operator Preventive Maintenance Frequency

Part	Frequency	Maintenance
Patient circuit: inspiratory and expiratory limbs	Several times a day or as required by the institution's policy.	• Check both limbs for water accumulation. • Empty and clean.
Water traps, and drain bag		Check and empty as needed.
Oxygen sensor calibration		From the ventilator setup screen, touch the *More Settings* tab. To calibrate the oxygen sensor, touch *Calibrate* in the oxygen sensor area of the screen. Reference *Oxygen sensor calibration testing*, p. 4-34 for information on testing the oxygen sensor calibration.
Inlet air filter bowl		• Replace bowl if it is cracked. • If any sign of moisture is visible, remove ventilator from use and contact service personnel.
Reusable inspiratory filter	• Before every use • After 15 days of continuous use in the inspiratory limb (replace) • Yearly or after 50 autoclave cycles (replace) • Whenever excess resistance is suspected	• Inspect and replace if cracked, crazed, or damaged. Sterilize between patients and circuit changes, or according to the institution's policy. Sterilize before non-destructive disposal, or dispose of filter according to the institution’s policy. • Run SST to check resistance of the inspiratory limb. • Use care when changing inspiratory filter to avoid filter damage and minimize the potential for introduction of particles.

Table 7-1. Operator Preventive Maintenance Frequency (Continued)

Part	Frequency	Maintenance
Reusable expiratory filter	• Before every use • After 15 days of continuous use in the exhalation limb (replace) • Yearly or after 50 autoclave cycles (replace) • Whenever excess resistance is suspected	• Inspect and replace if cracked, crazed, or damaged. Sterilize between patients and circuit changes, or according to the institution's policy. Sterilize before non-destructive disposal, or dispose of filter according to the institution's policy. • Run SST to check resistance of the expiratory limb and filter. • Use care when changing expiratory filter to avoid filter damage and minimize the potential for introduction of particles.
Condensate vial	• Several times a day or as required by the institution's policy • Before every use • After 15 days of continuous use with the expiratory filter (replace)	• Check and empty as needed. • Inspect and replace if cracked, crazed, or damaged. • Clean and sterilize between patients and circuit changes. Reference *Condensate Vial Cleaning*, p. 7-8 for instructions. Reference *Component Sterilization*, p. 7-24 for sterilization requirements. • Sterilize before non-destructive disposal, or according to the institution's policy.
Disposable inspiratory Filter	After 15 days of continuous use (discard)	Discard according to the institution's protocol.
Disposable expiratory Filter	After 15 days of continuous use (discard)	Discard according to the institution's protocol.

Table 7-1. Operator Preventive Maintenance Frequency (Continued)

Part	Frequency	Maintenance
Battery	When transferring battery to or from another ventilator	Disinfect by wiping with a damp cloth using one of the solutions listed. Reference *Surface Cleaning Agents*, p. 7-5 for approved cleaning agents.
Battery	Every three (3) years	Replace
Exhalation valve flow sensor assembly	When contamination is suspected. **NOTE:** The exhalation valve flow sensor assembly is removable and may be disinfected. **DO NOT STERILIZE** the exhalation valve flow sensor assembly.	Reference *Component Cleaning and Disinfection*, p. 7-6 and Reference *Exhalation Valve Flow Sensor Assembly Disinfection*, p. 7-13.
Exhalation valve flow sensor assembly.	Every 25 disinfection cycles. A disinfection cycle is defined as one disinfection event as described. Reference *Exhalation Valve Flow Sensor Assembly Disinfection*, p. 7-13.	Replace. Run flow sensor calibration, exhalation valve calibration, EST and SST after replacing the exhalation valve flow sensor assembly.

Caution:
Use specified cleaning, disinfecting, and sterilization agents and procedures for the appropriate part as instructed.

7.4 Surface Cleaning of Exterior Surfaces

External surfaces of the GUI, BDU, and ventilator base may become soiled and should be cleaned periodically.

To clean the GUI, BDU, and ventilator base surfaces

1. Moisten a soft cloth with one of the surface cleaning agents listed or use Sani-Cloths (PDI, Inc.). Reference *Surface Cleaning Agents*, p. 7-5.
2. Wipe the GUI, BDU, and ventilator base, removing any dirt or foreign substances.
3. Dry all components thoroughly.
4. If necessary, vacuum any cooling vents on the GUI and BDU with an electrostatic discharge (ESD)-safe vacuum to remove any dust.

Table 7-2. Surface Cleaning Agents

Part	Procedure	Comments/Cautions
Ventilator exterior (including touch screen and flex arm	Wipe clean with a cloth dampened with one of the cleaning agents listed below or equivalent. Use a damp cloth and water to rinse off chemical residue as necessary.	Do not allow liquid or sprays to penetrate the ventilator openings or cable connections.
	Mild dish washing detergent solution	Do not attempt to sterilize the ventilator by exposure to ethylene oxide (ETO) gas.
	Isopropyl alcohol (70% solution)	Do not use pressurized air to clean or dry the ventilator, including the GUI cooling vents.
	Bleach (10% solution)	Do not submerge the ventilator or pour cleaning solutions over or into the ventilator
	Window cleaning solution (isopropyl alcohol and ammonia)	
	Ammonia (15% solution)	
	Hydrogen peroxide (3% solution)	
	Formula 409® cleaner (Clorox Company)	
	CaviCide® surface disinfectant (Metrex Research Corporation)	
	Control III® germicide (Maril Products, Inc.)	
	Virox (spray or pre-wipes) (Virox Technologies Inc.)	
	Mr. Muscle Window & Glass (SC Johnson	
	Sani Cloths (PDI, Inc.)	
	[Propan-2-ol, Isopropanol, Isopropyl Alcohol][1]	

Table 7-2. Surface Cleaning Agents (Continued)

Part	Procedure	Comments/Cautions
Ventilator cooling vents	Vacuum the vents at the back of the GUI and BDU to remove dust.	N/A

1. Chemicals stated are the generic equivalents of Mr. Muscle Window & Glass

7.5 Component Cleaning and Disinfection

WARNING:
To avoid microbial contamination and potential performance problems, do not clean, disinfect, or reuse single-patient use (SPU) or disposable components. Discard per local or institutional regulations.

Risks associated with reuse of single-patient use items include but are not limited to microbial cross-contamination, leaks, loss of part integrity, and increased pressure drop. When cleaning reusable components, do not use hard brushes or implements that could damage surfaces.

Table 7-3. Component Cleaning Agents and Disinfection Procedures

Part	Cleaning Agent/Procedure	Comments/Cautions
Exhalation valve flow sensor assembly	Reference *Exhalation Valve Flow Sensor Assembly Disinfection*, p. 7-13 for specific instructions. • Cidex® (2.5%) (ASP) • Sporox® II (Sultan) • Cidex OPA® (ASP) .	**Do not drop the exhalation valve flow sensor assembly or handle roughly during disinfection or storage**.
Reusable patient circuit tubing	Disinfect per manufacturer's instructions-for-use.	• Inspect for nicks and cuts, and replace if damaged. • Run SST to check for leaks when reinstalling the circuit or when installing a new circuit.

Table 7-3. Component Cleaning Agents and Disinfection Procedures (Continued)

Part	Cleaning Agent/Procedure	Comments/Cautions
Disposable patient circuit tubing	Discard	Discard per the institution's protocol.
Breathing circuit in-line water traps	Disinfect per manufacturer's instructions-for-use.	• Inspect water traps for cracks and replace if damaged. • Run SST to check for leaks when reinstalling the circuit or when installing new components.
Breathing circuit components	Disinfect per manufacturer's instructions-for-use.	• Inspect components for nicks and cuts, and replace if damaged. • Run SST to check for leaks when reinstalling the circuit or when installing a new components.
Disposable drain bag and tubing (single unit)	Discard when filled to capacity or when changing patient circuit.	N/A
Inlet air filter bowl	Wash the bowl with mild soap solution, if needed.	• Avoid exposing the inlet air filter bowl to aromatic solvents, especially ketones. • Replace if cracks or crazing are visible.
Battery	Wipe with a damp cloth using one of the cleaning agents listed. Reference *Surface Cleaning Agents*, p. 7-5.	Do not immerse the battery or get the contacts wet.
Cooling fan filter	Clean every 250 hours or as necessary.	Wash in mild soap solution, rinse, and air dry.
Expiratory filter	Reference *Expiratory Filter Cleaning*, p. 7-9 for **cleaning** instructions. • Metrizyme (Metrex Research Corporation) • ENZOL® (ASP)	Reference expiratory filter instructions-for-use (IFU) for sterilization instructions.

Table 7-3. Component Cleaning Agents and Disinfection Procedures (Continued)

Part	Cleaning Agent/Procedure	Comments/Cautions
Condensate vial	Reference *Condensate Vial Cleaning*, p. 7-8 for cleaning instructions. • Metrizyme (Metrex Research Corporation) • ENZOL® (ASP)	Clean condensate vial
Other accessories	Follow manufacturer's instructions-for-use.	N/A

To clean parts

1. Wash parts in warm water using a mild soap solution.
2. Thoroughly rinse parts in clean, warm water (tap water is acceptable) and wipe dry.
3. Clean or disinfect ventilator surfaces and component parts per the procedures listed for each component. Reference *Surface Cleaning Agents*, p. 7-5. Reference *Component Cleaning Agents and Disinfection Procedures*, p. 7-6 for acceptable cleaning and disinfecting agents.
4. Visually inspect the components for cracks or other damage prior to use.
5. Dispose of damaged parts according to the institution's policy.

Whenever replacing or reinstalling a component, run SST before ventilating a patient.

7.5.1 Condensate Vial Cleaning

Reference *Condensate Vial*, p. 7-9 when following the condensate vial cleaning instructions.

Note:
The o-ring (1) should remain in place during cleaning.

To clean the condensate vial

1. Un-cap (2) the drain port from the condensate vial, but do not detach the retainer (3).

2. Rinse the condensate vial in water to remove any accumulations prior to cleaning.
3. Wipe the condensate vial assembly with the suggested cleaning solution to remove any accumulated material. The vial assembly may be fully immersed in the cleaning solution. Reference *Component Cleaning Agents and Disinfection Procedures*, p. 7-6 for the proper condensate vial cleaning solution.
4. Rinse the vial assembly with clean water. The assembly may be fully immersed to rinse.
5. Wipe the condensate vial dry.

Figure 7-1. Condensate Vial



1	O-ring	3	Retainer
2	Drain cap		

7.5.2 Expiratory Filter Cleaning

Reference the photos in this section when cleaning the expiratory filter.

liquid. To avoid retaining harmful residues, do not immerse housing or filter medium in liquid or sterilize using ethylene oxide (ETO).

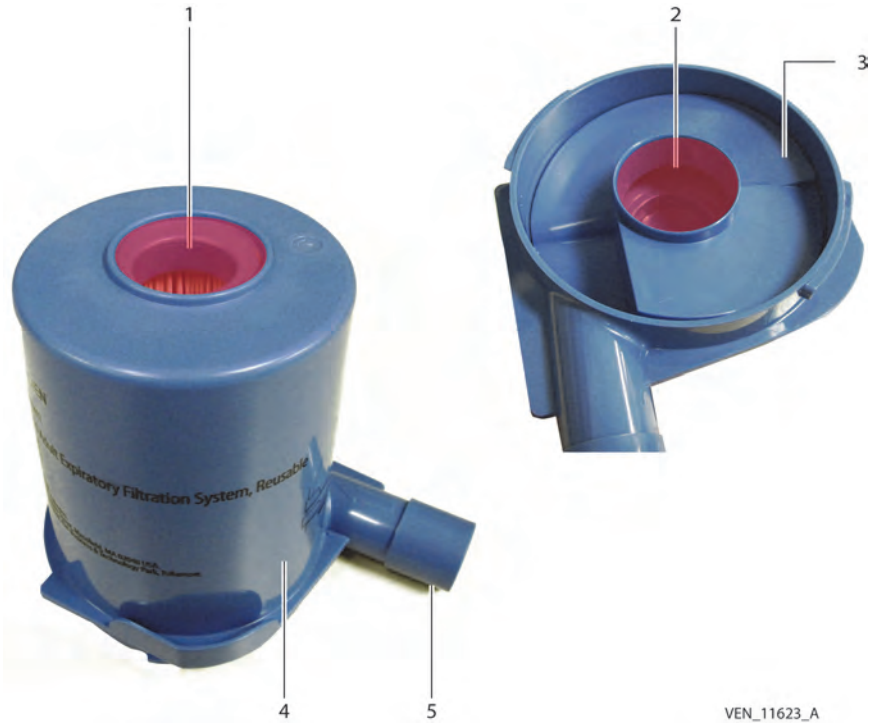
Caution:
Do not immerse the expiratory filter in liquid cleaning agent. Use care to prevent the cleaning agent from making contact with the filter media inside the filter housing.

Note:
Follow the institution's protocol for handling, storage, and disposal of potentially biocontaminated waste.

To clean the expiratory filter

1. Spray or wipe down surfaces of the exterior housing and housing bottom with cleaning solution. Reference *Component Cleaning Agents and Disinfection Procedures*, p. 7-6, for appropriate cleaning solutions. Use care to prevent the solution from contacting the filter media via the filter outlet, or entering the filter intake opening or from patient port.

Figure 7-2. Filter Top and Bottom Views



1	Filter outlet (top)	4	External housing
2	Filter intake opening (bottom)	5	**From patient** port
3	Housing bottom		

2. Wipe the interior surface of the from patient port with the solution to clean it.

Figure 7-3. From Patient Port



3. Allow to dry by orienting the filter in the upright position for the contact time period recommended by the solution's manufacturer.

Figure 7-4. Expiratory Filter Drying Orientation



4. Rinse all filter surfaces that were exposed to the cleaning solution with water, using care to prevent liquid from entering the filter.

5. Allow the filter housing to dry until all liquid has evaporated.

7.5.3 Exhalation Valve Flow Sensor Assembly Disinfection

Note:
Exhalation valve flow sensor assembly disinfection is not required on a routine basis but it may be disinfected. Reference *Component Cleaning Agents and Disinfection Procedures*, p. 7-6 for a list of appropriate disinfectants.

Note:
Follow the institution's infection control protocol for handling, storage, and disposal of potentially bio-contaminated waste.

Caution:
To avoid damaging the hot film wire, do not insert fingers or objects into the center port when disinfecting the exhalation valve flow sensor assembly.

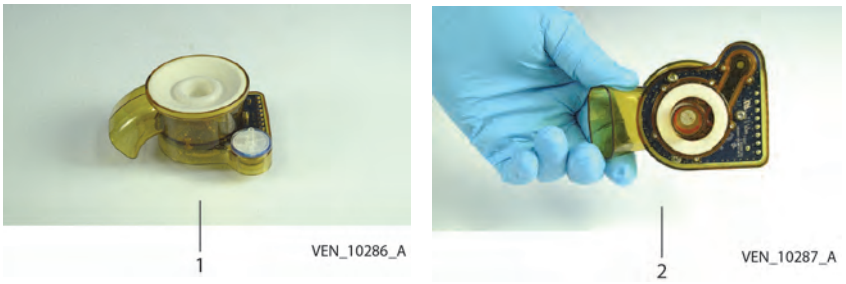
The exhalation valve flow sensor assembly contains the exhalation valve body, exhalation valve flow sensor, exhalation valve diaphragm, expiratory filter seal, and pressure sensor filter. The expiratory flow sensor electronics consist of the hot film wire and the thermistor. Since it is protected by the expiratory filter, it does not require or need replacement or disinfection on a regular basis. It is, however, removable and may be disinfected. Expected service life is 25 disinfection cycles.

Caution:
To avoid damage to the expiratory flow sensor element

- **Do not touch the hot film wire or thermistor in the center port**
- **Do not vigorously agitate fluid through the center port while immersed.**
- **Do not forcefully blow compressed air or any fluid into the center cavity.**
- **Do not drop or handle roughly during disinfection or storage.**

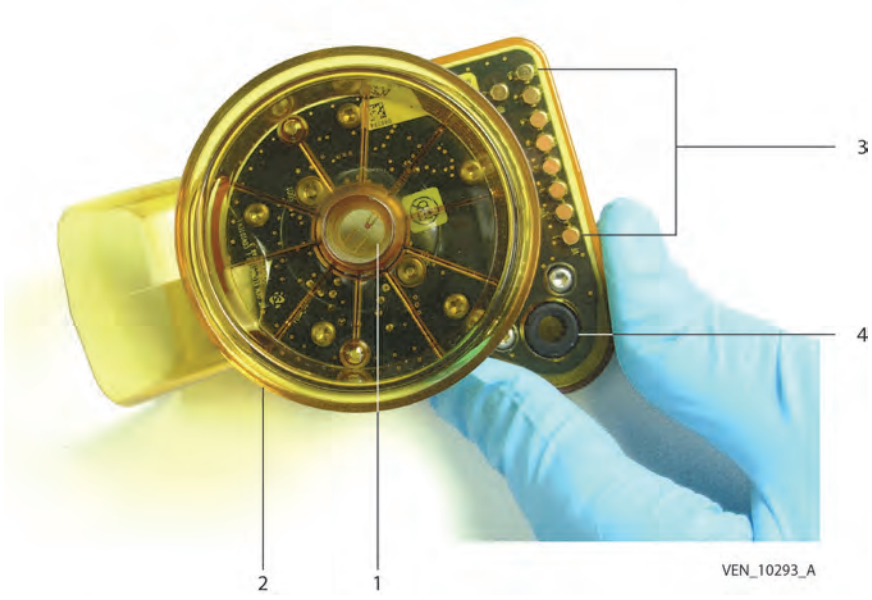
WARNING:
Damaging the flow sensor's hot film wire or thermistor in the center port can cause the ventilator's spirometry system to malfunction.

Figure 7-5. Exhalation Valve Flow Sensor Assembly



1	Top view	2	Bottom view

Figure 7-6. Exhalation Valve Flow Sensor Components



1	Hot film wire and thermistor	3	Electrical contacts
2	Diaphragm sealing surface	4	Filter grommet

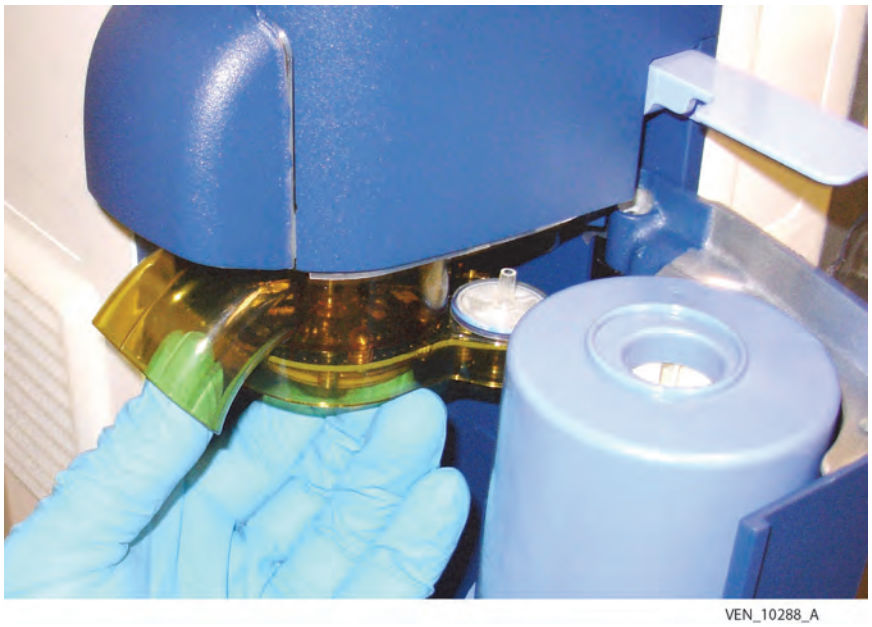
Removal

To remove the exhalation valve flow sensor assembly

1. Lift up on the expiratory filter latch and open the expiratory filter door.
2. With thumb inserted into the plastic exhalation port and four (4) fingers under the exhalation valve flow sensor assembly, pull it down until it snaps out. **To avoid**

damaging the flow sensor element, do not insert fingers into the center port.

Figure 7-7. Exhalation Valve Flow Sensor Assembly Removal



To remove disposable components of the exhalation valve flow sensor assembly

1. Remove and discard the exhalation valve diaphragm, the exhalation valve filter seal, and the pressure sensor filter. Pinch the expiratory filter seal between two fingers to remove it.

Figure 7-8. Exhalation Valve Diaphragm Removal



Figure 7-9. Expiratory Filter Seal Removal

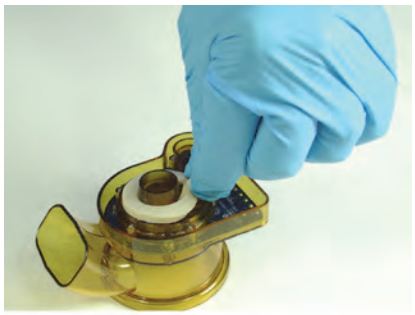
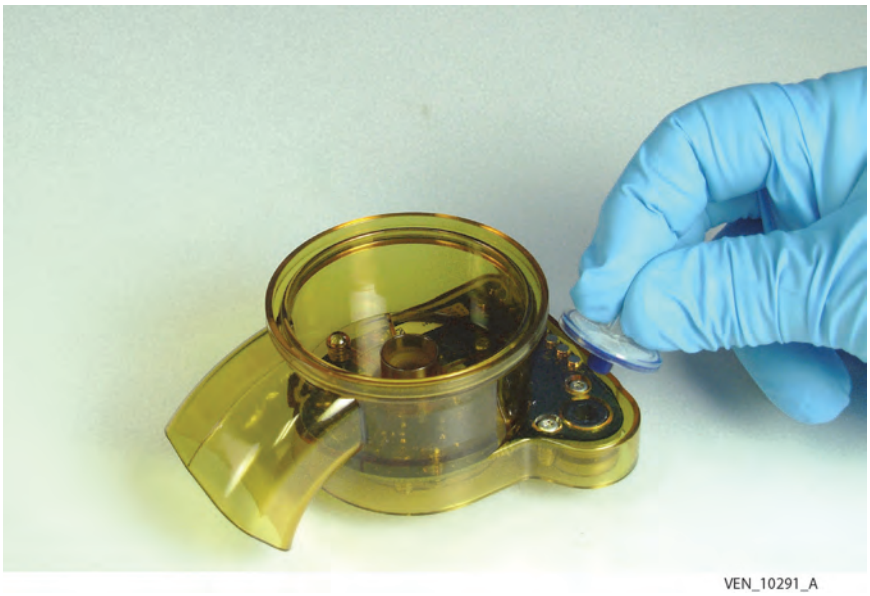


Figure 7-10. Pressure Sensor Filter Removal



2. Dispose of removed items according to the institution's protocol. Follow local governing ordinances regarding disposal of potentially bio-contaminated waste.

Disinfection

WARNING:
Do not steam autoclave the exhalation valve flow sensor assembly or sterilize with ethylene oxide gas. Either process could cause the ventilator's spirometry system to malfunction when reinstalled in the ventilator.

WARNING:
Use only the disinfectants described. Reference *Component Cleaning Agents and Disinfection Procedures*, p. 7-6. Using disinfectants not recommended by Covidien may damage the plastic enclosure or electronic sensor components, resulting in malfunction of the ventilator's spirometry system.

WARNING:
Follow disinfectant manufacturer's recommendations for personal protection (such as gloves, fume hood, etc.) to avoid potential injury.

1. Pre-soak exhalation valve flow sensor assembly in the enzymatic solution.Reference *Operator Preventive Maintenance Frequency*, p. 7-2. The purpose for this pre-soak is to break down any bio-film that may be present. Follow manufacturer's instructions regarding duration of soak process.

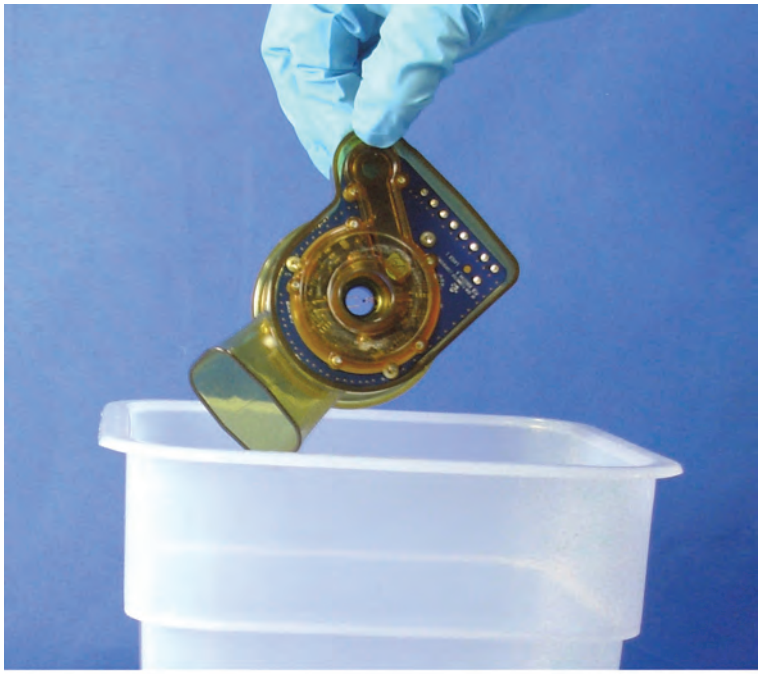
Caution:
Do not use any type of brush to scrub the exhalation valve flow sensor assembly, as damage to the flow sensing element could occur.

2. Rinse in clean, de-ionized water.

3. Prepare the chemical disinfectant according to the manufacturer's instructions or as noted in the institution's protocol. Reference *Component Cleaning Agents and Disinfection Procedures*, p. 7-6 for the proper disinfecting agents.

4. Immerse the in the disinfectant solution, oriented as shown, and rotate to remove trapped air bubbles in the its cavities. Keep immersed for the minimum time period by the manufacturer or as noted in the institution's protocol.

Figure 7-11. Immersion Method



5. At the end of the disinfecting immersion period, remove and drain all disinfectant. Ensure all cavities are completely drained.

Rinsing

1. Rinse the exhalation valve flow sensor assembly using clean, de-ionized water in the same manner used for the disinfection step.

2. Drain and **repeat rinsing three times** with clean, de-ionized water.

WARNING:
Rinse according to manufacturer's instructions. Avoid skin contact with disinfecting agents to prevent possible injury.

3. After rinsing in de-ionized water, immerse in a clean isopropyl alcohol bath for approximately 15 seconds. Slowly agitate and rotate to empty air pockets.

Drying

1. Dry in a low temperature warm air cabinet designed for this purpose. Covidien recommends a convective drying oven for this process, with temperature not exceeding 60°C (140°F).

Caution:
Exercise care in placement and handling in a dryer to prevent damage to the assembly's flow sensor element.

Inspection

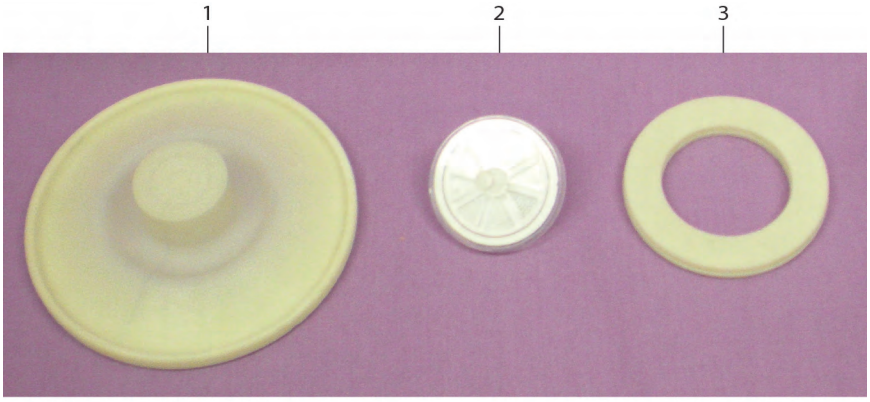
Reference *Exhalation Valve Flow Sensor Components*, p. 7-15 while inspecting the exhalation valve flow sensor assembly.

1. Inspect the plastic body, diaphragm sealing surface, filter grommet and the seal groove on the bottom side for any visible damage, degradation, or contamination.
2. Inspect electrical contacts for contaminating film or material. Wipe clean with a soft cloth if necessary.
3. Inspect the hot film wire and thermistor in the center port for damage and for contamination.**DO NOT ATTEMPT TO CLEAN EITHER OF THESE**. If contamination exists, rinse again with de-ionized water. If rinsing is unsuccessful or hot film wire or thermistor is damaged, replace the exhalation valve flow sensor assembly.

7.5.4 Exhalation Valve Flow Sensor Assembly Reassembly

The following illustration shows the reprocessing kit:

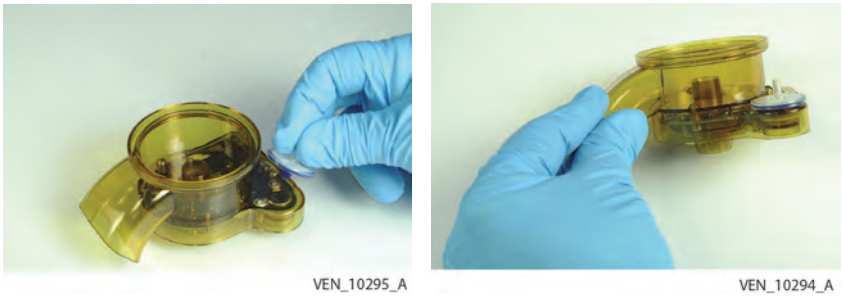
Figure 7-12. Exhalation Valve Flow Sensor Assembly Reprocessing Kit



1	Diaphragm	3	Expiratory filter seal
2	Pressure sensor filter		

1. After drying the exhalation valve flow sensor assembly, remove the pressure sensor filter from the reprocessing kit and install its large diameter into the filter grommet with a twisting motion until flush with the plastic valve body, as shown. The narrow end faces out.

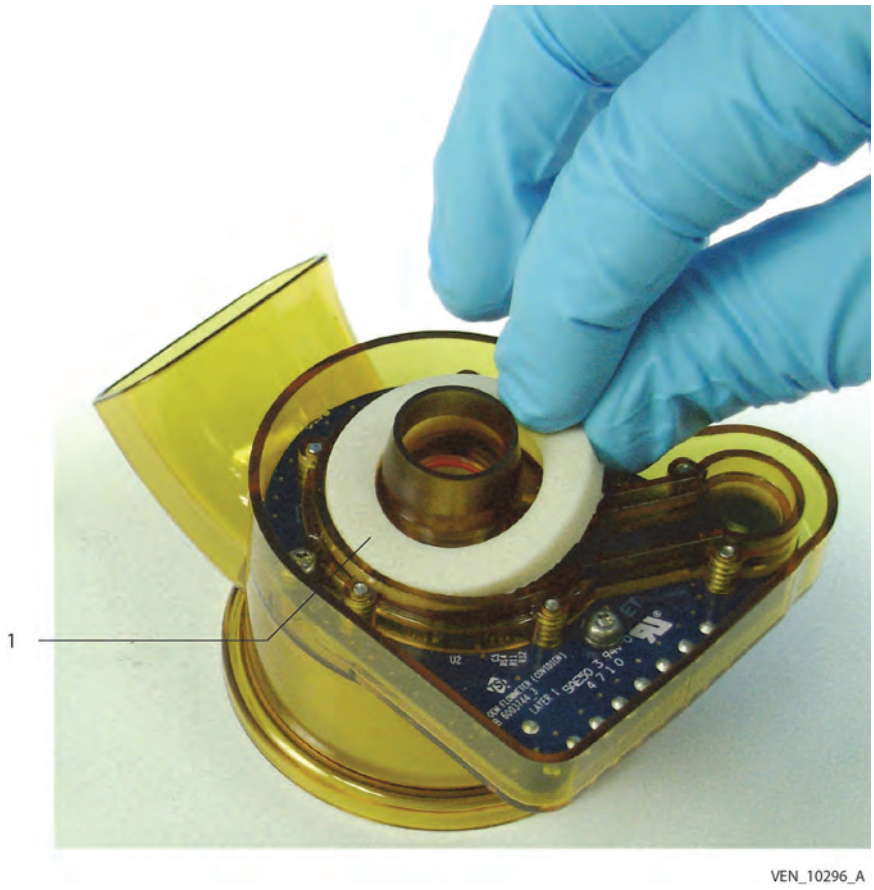
Figure 7-13. Installing the Pressure Sensor Filter



2. Remove the expiratory filter seal from the kit and turn the assembly so its bottom is facing up.

3. Install the seal into the recess with the flat side facing outward, away from the recess. Reference *Installing the Expiratory Filter Seal*, p. 7-22.

Figure 7-14. Installing the Expiratory Filter Seal



1 Flat side of seal

4. Remove the diaphragm from the kit and install it. The outer seal bead rests in the outer groove.

Figure 7-15. Installing the Diaphragm



1 Diaphragm bead located in exhalation valve flow sensor assembly's groove

5. Carefully inspect component placement and the complete assembly.

7.5.5 Exhalation Valve Flow Sensor Assembly Replacement

1. Replace the exhalation valve flow sensor assembly any time if cracked or damaged in use, or if a malfunction occurs during SST or EST.

2. Replace the assembly if damage is noted to the hot film wire and thermistor in the center port.

3. Perform required calibrations. Reference *Operator Preventive Maintenance Frequency*, p. 7-2.

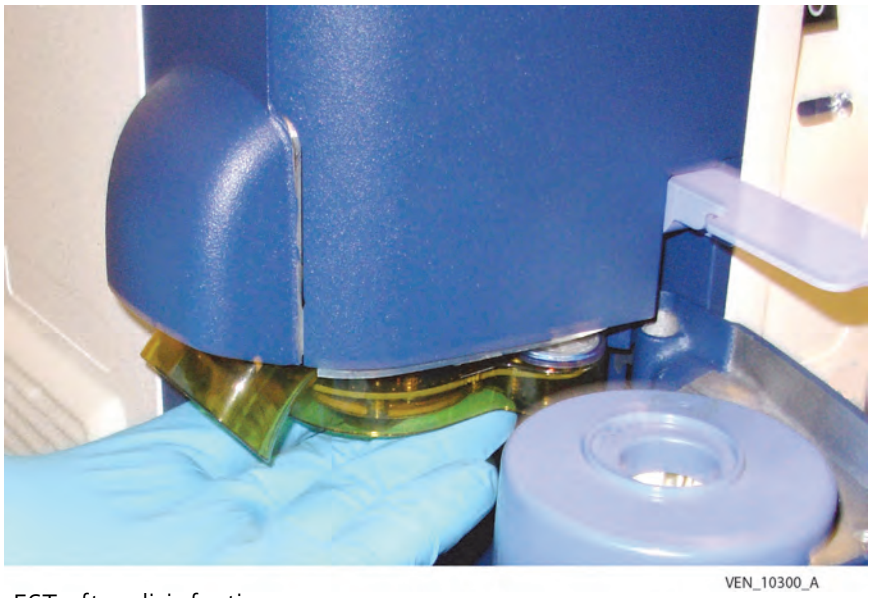
To install the exhalation valve flow sensor assembly into the ventilator

1. With the expiratory filter door open, insert the assembly directly under the exhalation valve and push straight up until it snaps into place. Reference *Installing the Exhalation Valve Flow Sensor Assembly*, p. 7-24. To avoid damaging the hot film wire, do not insert fingers into any opening.

2. Install the expiratory filter by sliding it onto the tracks in the door, and orienting the filter's **From Patient** port through the hole in the door.

3. Close expiratory filter door and lower expiratory filter latch.

Figure 7-16. Installing the Exhalation Valve Flow Sensor Assembly



4. Run EST after disinfection.

7.5.6 Storage

1. Pre-test the exhalation valve flow sensor assembly before storage by installing it into the ventilator and running SST to test the integrity of the breathing system. Reference *To run SST*, p. 3-48

2. After performing SST, remove the assembly and place it into a protective bag or similar covered container.

7.6 Component Sterilization

To sterilize parts

1. Sterilize per the component's instructions-for use or the steam sterilization procedure described. Reference *Sterilization Parameters*, p. 7-25 and *Component Sterilization Procedures* on *page 7-25*.

2. After the components are sterilized, visually inspect them for cracks or other damage.

3. Dispose of damaged parts according to the institution's policy.

Table 7-4. Sterilization Parameters

Autoclave sterilization
Effective sterilization occurs by pre-vac sterilization of wrapped goods (132°C for 4 minutes). Refer to pre-vac system manufacturer's program parameters or follow the steam sterilizer manufacturer's instructions. 1. Disassemble the component. 2. Clean the component. 3. Wrap each component in a legally marketed sterilization wrap that has been cleared by FDA for use in pre-vac sterilization using the parameters described above. 4. Sterilize the wrapped parts*. 5. Inspect the sterilized parts for damage, and discard if damaged. 6. Reassemble the component. 7. Install the component on the ventilator. 8. Run SST. *Follow pre-vac system manufacturer's instructions for use (IFU).

Table 7-5. Component Sterilization Procedures

Part	Procedure	Comments/Cautions
Reusable expiratory and inspiratory filters	Steam autoclave per manufacturer's instructions-for-use	• Do not chemically disinfect or expose to ETO gas • Check filter resistance using ventilator SST or other means before reuse. • Follow manufacturer's recommendations for reuse.
Expiratory filter condensate vial	Steam autoclave per manufacturer's instructions-for-use	• Inspect the condensate vial for cracks after processing. • Replace condensate vial if damaged

Table 7-5. Component Sterilization Procedures (Continued)

Part	Procedure	Comments/Cautions
Reusable drain bag tubing (short piece of tubing attached to drain bag) and clamp	Clean and autoclave the reusable tubing; clean the clamp. Reference *Surface Cleaning Agents*, p. 7-5 for approved cleaning agents.	N/A

Whenever replacing or reinstalling a component, run SST before ventilating a patient.

7.7 Service Personnel Preventive Maintenance

Covidien recommends only qualified service personnel perform preventive maintenance activities. Complete details are described in the *Puritan Bennett™ 980 Series Ventilator Service Manual*.

At ventilator startup, and in Service mode, the GUI and status display indicate when there are 500 hours or less before preventive maintenance is due.

7.8 Safety Checks

Covidien factory-trained service personnel should perform Extended Self Test (EST) on the ventilator after servicing it at the intervals specified in the table above. Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* for details on performing EST.

7.9 Inspection and Calibration

Ventilator inspection and calibration should be performed by Covidien factory-trained service personnel at the intervals specified in the table above.

7.10 Documentation

Covidien factory-trained service personnel should manually enter the service date, time, and nature of repair/preventive maintenance performed into the log using a keyboard on the GUI.

To manually document a service or preventive maintenance activity

1. Enter Service Mode.
2. Select the *Logs* tab.
3. Select the *Service Log* tab.
4. Select *Add Entry*, and using the buttons to the right of each line, complete the entry.
5. Touch *Accept* when complete.

7.11 Storage for Extended Periods

To store the ventilator

1. Clean the unit thoroughly.
2. Remove any batteries and accessories.

To return the ventilator to service

1. Replace batteries.
2. Recharge batteries prior to patient ventilation. If batteries are older than three (3) years, use new batteries.
3. Perform EST and SST prior to patient ventilation.

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8 Troubleshooting

8.1 Overview

This chapter contains information regarding ventilator logs on the Puritan Bennett™ 980 Series Ventilator.

WARNING:
To avoid a potential electrical shock, do not attempt to correct any electrical problem with the ventilator while it is connected to AC power.

8.2 Problem Categories

For the Puritan Bennett™ 980 Series Ventilator *Operator's Manual*, troubleshooting is limited to responding to ventilator alarms and reviewing various ventilator logs. For detailed alarm information, including how to respond to alarms, *Reference Chapter 6* to address individual alarms that may occur during ventilator use. Qualified service personnel who have attended the Covidien training class for Puritan Bennett 980 Series Ventilators should consult the *Puritan Bennett™ 980 Series Ventilator Service Manual* for detailed repair information and ventilator diagnostic codes.

8.3 How to Obtain Ventilator Service

To obtain service for the ventilator, call Covidien Customer Service at 1.800.635.5267 and follow the prompts.

8.4 Used Part Disposal

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. Discard all damaged parts removed from the ventilator during the maintenance procedures according to your institution's protocol. Sterilize contaminated parts before non-destructive disposal.

8.5 Ventilator Logs

The ventilator uses various logs to store event information for later retrieval when managing a patient's treatment. Some of the logs are accessible during ventilation and some logs are only available to Covidien personnel when the ventilator is in Service mode. The Puritan Bennett™ 980 Series Ventilator *Service Manual* gives more details regarding logs available to qualified service personnel.

When New Patient is selected during ventilator setup, patient data, ventilator settings, and alarm logs are cleared, but this information is available for Service personnel review following New Patient selection when the ventilator is set up.

- **Alarms Log —** The alarm log records up to 1000 alarms that have occurred, whether they have been reset or autoreset, the priority level, and their analysis messages. The alarm log is accessible during normal ventilation and in Service mode. A date- and time-stamped entry is made in the log whenever an alarm is detected, escalated, reset or auto-reset. An entry is also made when an alarm silence interval begins, ends, or is canceled. If one or more alarms have occurred since the last time the alarm log was viewed, a triangular icon appears on the GUI indicating there are unread items. The alarm log is stored in non-volatile memory (NVRAM) and may be re-displayed after the ventilator's power is cycled.If the ventilator enters BUV for any reason, this is also entered into the alarm log. The alarm log is cleared by setting the ventilator up for a new patient.

- **Settings Log —** The settings log records changes to ventilator settings for retrospective analysis of ventilator-patient management. The time and date, old and new settings. and alarm resets are recorded. A maximum of 500 settings changes can be stored in the log. The settings log is cleared when the ventilator is set up for a new patient. The settings log is accessible in normal ventilation mode and Service mode.

- **Patient Data Log —** This log records every minute (up to 4320 patient data entries) consisting of date and time of the entry, patient data name, and the patient data value during ventilator operation. It is cleared when the ventilator is set up for a new patient. Three tabs are contained in the patient data log:

  - Vital Patient data — The log contains the same information that the clinician has configured in the patient data banner at the top of the GUI. If the patient data parameters in the banner are changed, these changes are reflected the next time the patient data log is viewed.

  - Additional Patient Data – 1 — This log corresponds to the patient data parameters set on page 1 of the additional patient data banner. A total of 15 parameters are stored here, consisting of date and time of the entry (recorded every minute), patient data name, and the patient data value during ventilator operation.

  - Additional Patient Data – 2 — This log corresponds to the patient data parameters set on page 2of the additional patient data banner. A total of ten (10) parameters are stored here, consisting of date and time of the entry (recorded every minute), patient data name, and the patient data value during ventilator operation.

- **Diagnostic Log —** The Diagnostic Log is accessible during normal ventilation and Service modes and contains tabs for the System Diagnostic Log (default), the System Communication Log, and the EST/SST Diagnostic Log. The diagnostic log contains tabs for the following:

  - System Diagnostic Log — The System Diagnostic Log contains the date and time when an event occurred, the type of event, the diagnostic code(s) associated with the event and any notes.Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* (10078090) for specific information contained in the System Diagnostic Log. The diagnostic log is not cleared when the ventilator is set up for a new patient.

  - System Communication Log — This log contains diagnostic information generated by the ventilator's communication software. Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* (10078090) for specific information contained in the System Communication Log.

  - EST/SST Diagnostic Log — The EST/SST diagnostic log displays the time, date, test/event, system code (reference the Puritan Bennett™ 980 Series Ventilator Service Manual), type, and notes.

- **EST/SST status log —** The EST and SST status log displays the time, date, test, test status (passed or failed).

- **General Event log —** The general event log contains ventilator-related information not found in any other logs. It includes changes in alarm volume, when the ventilator entered and exited Stand-By, GUI key presses, respiratory mechanics maneuvers, O_2 calibration, patient connection, elevate O_2, and warning notifications. The General event log can display up to 256 entries and is not cleared upon new patient setup.

- **Service Log —** The service log is accessible during normal ventilation and Service modes and contains the nature and type of the service, reference numbers specific to the service event (for example, sensor and actuator ID numbers), manual and automatic serial number input, and the time and date when the service event occurred. It is not cleared upon new patient setup.

To view ventilator logs



1. Touch the clipboard icon in the constant access icon area of the GUI. The log screen appears with tabs for the various logs.
2. Touch the tab of the log desired.

3. View the information for each parameter desired.

Figure 8-1. Log Screen



1 Individual logs tabs

2 Pages contained in the log being viewed

Ventilator logs can be saved by entering Service mode, and downloading them via the ethernet port. Reference the Puritan Bennett™ 980 Series Ventilator *Service Manual* for instructions on downloading ventilator logs.

8.6 Diagnostic Codes

Refer to the diagnostic log for the codes generated during patient ventilation. For a more information on the diagnostic codes, reference the Puritan Bennett™ 980 Series Ventilator *Service Manual* or contact Covidien Technical Support.

9 Accessories

9.1 Overview

This chapter includes accessories that can be used with the Puritan Bennett™ 980 Series Ventilator. Reference *Covidien Accessories and Options*, p. 9-4 for part numbers of any items available through Covidien.

The following commonly available accessories from the listed manufacturers can be used with the ventilator system:

- **Filters** — DAR/Covidien, Puritan Bennett
- **Heated Humidification Systems** — Hudson RCI/Teleflex, Fisher & Paykel
- **Patient Circuits** — commonly available breathing circuits with standard ISO 15 mm/22 mm connection for neonatal, pediatric, and adult patients. Manufacturers include Fisher & Paykel, DAR, and Hudson RCI/Teleflex.
- **Masks** — ResMed, Respironics, Fisher & Paykel
- **Patient Monitoring Systems** — Reference *Connectivity to External Systems*, p. 5-21 for information on which systems can be used with the ventilator
- Nasal Interfaces — Hudson RCI/Teleflex, Fisher & Paykel, Argyle
- **Compressed air filter and water trap** — Covidien

WARNING:
The Puritan Bennett™ 980 Series Ventilator contains phthalates. When used as indicated, very limited exposure to trace amounts of phthalates may occur. There is no clear clinical evidence that this degree of exposure increases clinical risk. However, in order to minimize risk of phthalate exposure in children and nursing or pregnant women, this product should only be used as directed.

9.2 General Accessory Information

The patient circuit support arm (flex arm) can be fastened to the ventilator handle on either the right or left side. Flex arms used on the Puritan Bennett™ 840 Ventilator System can also be used on the Puritan Bennett™ 980 Ventilator System.

Figure 9-1. Ventilator with Accessories

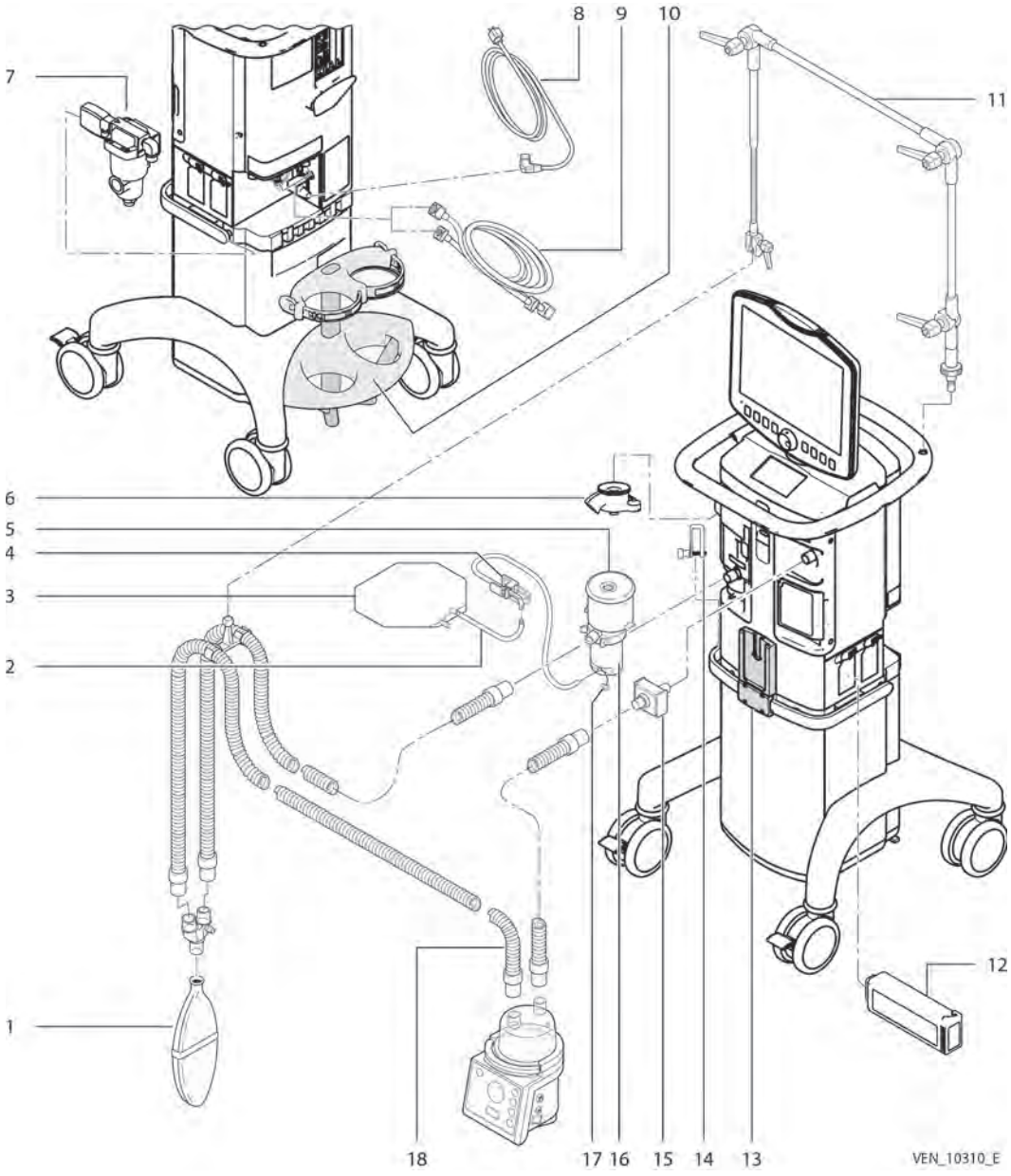
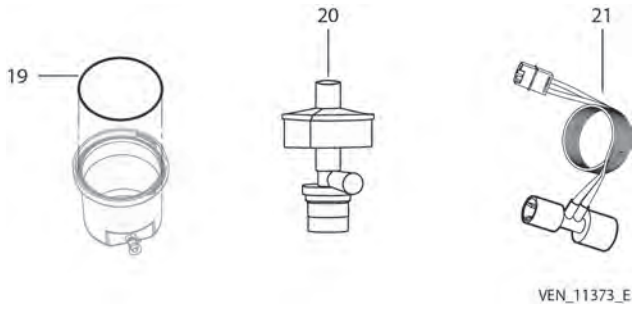


Figure 9-2. Additional Accessories



Reference *Ventilator with Accessories*, p. 9-3 and the figure above for the parts listed in the following table.

Note:
Occasionally, part numbers change. If in doubt about a part number, contact your local Covidien representative.

Table 9-1. Covidien Accessories and Options

Item number	Accessory or option description	Part number
1	Test lung	10005490
2	Drain Bag Tubing (package of 10)	4-048493-00
3	Drain Bag (package of 25)	4-048491-00
4	Drain Bag Tubing Clamp, reusable (package of 5)	4-048492-00
5	Pediatric-Adult Expiratory Filter[1]	10063033
	Pediatric-Adult Expiratory Filtration System (carton of 12)	10043551
6	980 FRU, Exhalation valve flow sensor	10097468
7	Wall air water trap	10086051

Table 9-1. Covidien Accessories and Options (Continued)

Item number	Accessory or option description	Part number
8	Power cord, 10A, RA, ANZ	10087151
	Power cord, 10A, RA, UK	10087159
	Power cord, 10A, RA, EU	10087155
	Power cord, 10A, RA, Japan	10087157
	Power cord, 10A, RA, British	10087152
	Power cord, 10A, RA, Switzerland	10087154
	Power cord, 10A, RA, USA	10081056
	Power cord, 10A, RA, Israel	10087156
	Power cord, 10A, RA, Brazil	10087160
	Power cord, 10A, RA, China	10087153
9	Air hose assembly; Norway, Sweden, Finland, Denmark, Greece, France	4-074696-00

Table 9-1. Covidien Accessories and Options (Continued)

Item number	Accessory or option description	Part number
	Air hose assembly; Australia, New Zealand	4-074712-00
	Air hose assembly; Canada	4-074709-00
	Air hose assembly; Italy, Switzerland, Spain, Belarus, Kazakhstan	4-074706-00
	Air hose assembly; Japan, Israel	10001777
	Air hose assembly; Poland, Portugal, South Africa	4-074703-00
	Air hose assembly; Switzerland	4-074707-00
	Air hose assembly; United States, Latin America	4-006541-00
	Air hose assembly; Germany, Luxembourg, Austria, Netherlands, Belgium, Croatia, Turkey, Russia, Slovenia, Serbia, Bulgaria, Romania	4-074714-00
	Air hose assembly; United Kingdom, Ireland, Switzerland, Hungary, Slovakia, Czech	4-074713-00
	Oxygen hose assembly; Norway, Sweden, Finland, Denmark, Greece, France	4-074697-00
	Oxygen hose assembly; Canada	4-074710-00
	Oxygen hose assembly, Italy, Switzerland, Spain, Belarus, Kazakhstan	4-074705-00
	Oxygen hose assembly; Japan, Israel	10001766
	Oxygen hose assembly; Poland, Portugal, South Africa	4-074705-00
	Oxygen hose assembly; Switzerland	4-074708-00
	Oxygen hose assembly; United States, Latin America	4-001474-00
	Oxygen hose assembly; Germany, Luxembourg, Austria, Netherlands, Belgium, Croatia, Turkey, Russia, Slovenia, Serbia, Bulgaria, Romania	4-074715-00
	Oxygen hose assembly; United Kingdom, Ireland, Switzerland, Hungary, Slovakia, Czech	4-074698-00
	For countries not identified, contact your local Covidien representative for the proper air and oxygen hose part numbers.	
10	Cylinder mount for compressed Air and O_2 gas	10086050
11	Flex arm assembly	4-032006-00
12	Rechargeable Lithium Ion battery	10086042

Table 9-1. Covidien Accessories and Options (Continued)

Item number	Accessory or option description	Part number
13	Humidifier bracket	10086049
14	Drain Bag Clip	10087137
15	Inspiratory bacterial filter, reusable (Re/Flex)	4-074600-00
	Inspiratory bacterial filter, disposable, (carton of 12) (DAR)	351U5856
16	Condensate vial, reusable	10063031
17	Condensate vial drain cap	4-074613-00
18	Assy, Patient Circuit, Heated Wire, Adult (reusable)	G-061235-00
	Assy, Patient Circuit, Heated Wire, Pediatric Patient circuit, Pediatric, reusable	G-061237-00
	Assy, Patient Circuit, Pediatric, Reusable	G-061223-00
	Patient circuit, Adult, single use	6-003030-00
	Ventilator breathing circuit, Neonatal disposable, DAR™ (not available in USA)	3078447
	Ventilator breathing circuit, Neonatal, disposable, Hudson RCI/Teleflex	780-06
	Ventilator breathing circuit, Neonatal, disposable, Fisher & Paykel	RT235
19	O-ring seal, condensate vial, reusable	10085527
20	Neonatal expiratory filtration system, disposable, with condensate vial	4-076900-00
21	Proximal Flow monitoring sensor (disposable, 10/box)	10047078
Not shown	Exhalation valve module reprocessing kit (6/carton)	10086048
Hardware options		
Not shown	Gold standard test circuit, 21 inch (for performing EST)	4-018506-00
--	Proximal Flow Monitoring Option	10084331
Software options		
Not shown	Leak Sync Software	10086418
Not shown	Leak Sync Software Upgrade	10096528
Not shown	IE Sync Software	10086354
Not shown	IE Sync Software Upgrade	10096529

Table 9-1. Covidien Accessories and Options (Continued)

Item number	Accessory or option description	Part number
Not shown	NeoMode 2.0 Software	10086743
Not shown	NeoMode 2.0 Software Upgrade	10096526
Not shown	PAV+ Software	10086283
Not shown	PAV+ Software Upgrade	10096530
Not shown	BiLevel 2.0 Software	10086682
Not shown	BiLevel 2.0 Software Upgrade	10096527

1. Reusable filtration system does not include condensate vial. Reusable condensate vial must be ordered separately.

10 Theory of Operations

10.1 Overview

This chapter provides specific details on breath delivery functions of the Puritan Bennett™ 980 Series Ventilator. The chapter is organized as shown below.

Section Number	Title	Page
10.1	*Overview*	*p. 10-1*
10.2	*Theoretical Principles*	*p. 10-3*
10.3	*Applicable Technology*	*p. 10-3*
10.4	*Inspiration — Detection and initiation*	*p. 10-4*
10.5	*Exhalation — Detection and Initiation*	*p. 10-9*
10.6	*Compliance and BTPS Compensation*	*p. 10-13*
10.7	*Mandatory Breath Delivery*	*p. 10-17*
10.8	*Spontaneous Breath Delivery*	*p. 10-22*
10.9	*A/C Mode*	*p. 10-31*
10.10	*SIMV Mode*	*p. 10-34*
10.11	*Spontaneous (SPONT) Mode*	*p. 10-39*
10.12	*Apnea Ventilation*	*p. 10-41*
10.13	*Detecting Occlusion and Disconnect*	*p. 10-45*
10.14	*Respiratory Mechanics*	*p. 10-49*
10.15	*Ventilator Settings*	*p. 10-57*
10.16	*Safety Net*	*p. 10-71*
10.17	*Power On Self Test (POST)*	*p. 10-76*
10.18	*Short Self Test (SST)*	*p. 10-77*
10.19	*Extended Self Test (EST)*	*p. 10-77*

WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

The gas supplies to which the ventilator are connected must be capable of delivering 200 L/min flow with the supply pressure between 35 psig and 87 psig (241.8 kPa to 599.8 kPa). These supplies may be compressed air from an external source (wall or bottled) air or oxygen.

Air and oxygen hoses connect directly to fittings at the rear of the breath delivery unit (BDU). The flow of each gas is metered by a Proportional Solenoid (PSOL) valve to achieve the desired mix in the Mix Module. The flow through each PSOL is monitored by separate flow sensors to ensure the accuracy of the mix. The mixed gases then flow to the Inspiratory Module.

The blended gas in the Inspiratory Module is metered by the Breath Delivery PSOL and monitored by the Breath Delivery Flow Sensor to ensure that the gas is delivered to the patient according to the settings specified by the operator. Delivered tidal volumes are corrected to standard respiratory conditions (BTPS) to ensure consistent interpretation by the clinician. The Inspiratory Module also incorporates the Safety Valve, which opens to vent excess pressure and allows the patient to breathe room air (if able to do so) in the event of a serous malfunction.

Breathing gas exits the Inspiratory Module, passes through an internal bacteria filter leaving the ventilator via the **To Patient** port. The ventilator breathing circuit, including the external bacteria filter and humidification means, carries the breathing gas to the patient.

Exhaled gas leaves the expiratory limb of the breathing circuit through the **From Patient** port. The gas is conducted through a condensate vial, the expiratory bacteria filter and the exhalation valve assembly (EVQ) which includes a pressure sensing port, a flow sensor, and the exhaust port. The gas then flows through the exhalation valve, which actively controls PEEP while minimizing pressure overshoot and relieving excess pressures.

Pressure transducers in the inspiratory pneumatic system (PI) and exhalation compartment (PE) monitor pressures for accurately controlling breath delivery.

10.2 Theoretical Principles

This theory of operations is described mainly from a clinical standpoint, discussing how the ventilator responds to various patient inputs, but also including a general description of the ventilator's components and how they work together to manage breath delivery.

10.3 Applicable Technology

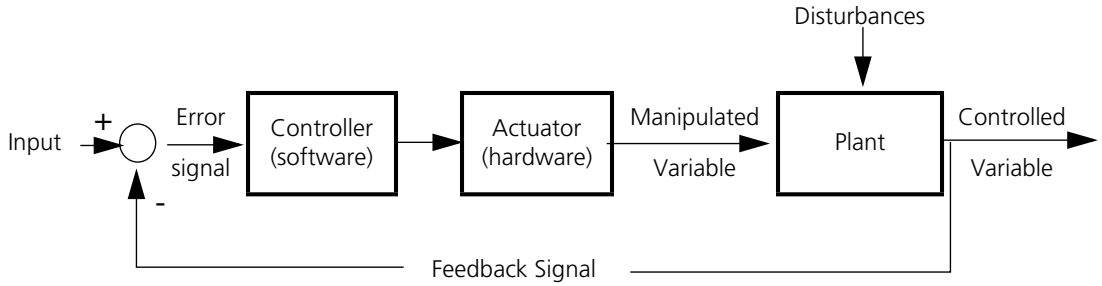
The ventilator's control is provided by Breath Delivery (BD) and Graphical User Interface (GUI) Central Processing Units (CPUs). The BD CPU manages all breath delivery functions and provides background checks on the subsystems required for breath delivery. The GUI CPU controls the primary display, operator input devices, and the alarm system. The status display, a small, non-interactive LCD display located on the Breath Delivery Unit (BDU) is controlled by its own processor. Reference *Status Display*, p. 2-28 for more information.

USB, Ethernet, and HDMI interfaces are provided on the ventilator. The USB interface supports items such as transferring data to an external monitor via a serial -over-USB protocol and saving screen captures to a memory storage device or flash drive. Reference *To configure Comm ports*, p. 5-4 for information on serial-over-USB data transfer. The Ethernet interface is used by qualified service personnel for accessing ventilator logs and performing software options installation, and the HDMI interface provides the ability to display the GUI screen on an external video display device.

Pressure and flow sensors in the inspiratory and expiratory modules to manage breath delivery processes. Sensor signals are used as feedback to the breath delivery PSOL and exhalation valve controllers. Additional flow and pressure sensors are used in the mix module to control the breathing gas composition. In addition, gas temperature is measured for temperature compensation of flow readings. Atmospheric pressure is measured in the inspiratory module and used for BTPS compensation. The sensor signals are filtered using anti-aliasing filters and sampled with A/D converters. Additional low-pass filters precondition the signals, the signals are then used for controls and display purposes.

Closed-loop control is used to maintain consistent pressure and flow waveforms in the face of changing patient/system conditions. This is accomplished by using the output as a feedback signal that is compared to the operator-set input. The difference between the two is used to drive the system toward the

desired output. For example, pressure-control modes use airway pressure as the feedback signal to control gas flow from the ventilator. Reference the figure below. This diagram shows a schematic drawing of a general feedback control system. The input is a reference value (e.g., operator preset inspiratory pressure) that is compared to the actual output value (e.g., instantaneous value of airway pressure). The difference between those two values is the error signal. The error signal is passed to the controller (e.g., the software control algorithm). The controller converts the error signal into a signal that can drive the actuator (e.g., the hardware drivers and valves) to cause a change in the manipulated variable (e.g., inspiratory flow).



Note:
In the diagram above, the "plant" is the patient and the connected breathing circuit.

10.4 Inspiration — Detection and initiation

When ventilator inspiration occurs, it is called triggering. Breaths are delivered to the patient based on ventilator settings the practitioner has entered and are determined by pressure, flow, or time measurements, or operator action. The ventilator uses the following methods to trigger an inspiration:

- Pressure triggering (P_{-TRIG})
- Flow triggering ($\dot{V}_{-TRIG}$)
- Time-triggered
- Operator-initiated
- IE Sync triggered (if the IE Sync option is installed) (in SPONT mode, only)

Note:
Reference *Appendix C* in this manual for more information on IE Sync.

If the ventilator detects a drop in pressure at the circuit wye or when there is a decrease in base flow measured at the exhalation valve, the patient is said to trigger the breath. Mandatory breaths triggered by the patient are referred to as ***PIM*** or patient-initiated mandatory breaths.

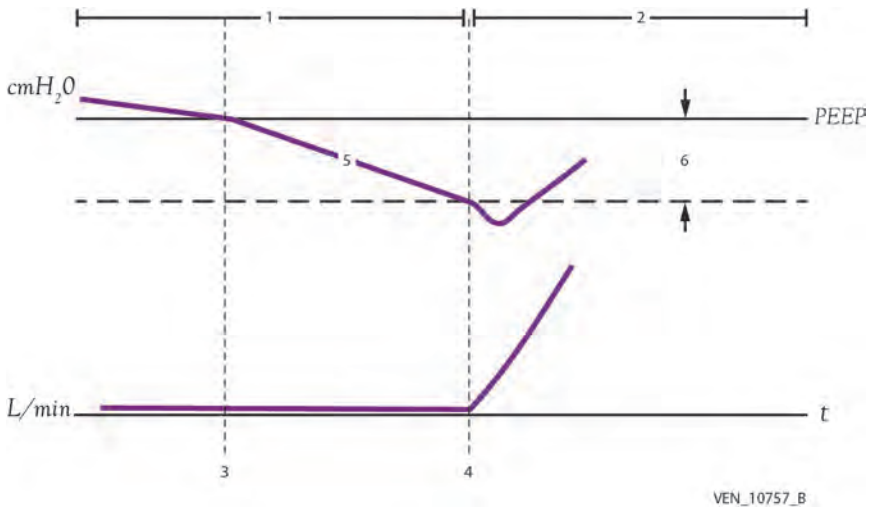
All spontaneous breaths are patient-initiated, and are also triggered by a decrease in circuit pressure or measured base flow indicating the patient is initiating an inspiration.

Another term, ***autotriggering***, is used to describe a condition where the ventilator triggers a breath in the absence of the patient's breathing effort. Autotriggering can be caused by inappropriate ventilator sensitivity settings, water in the patient circuit, or gas leaks in the patient circuit.

10.4.1 Pressure Triggering

If pressure triggering (P_{-TRIG}) is selected, the ventilator transitions into inspiration when the pressure at the patient circuit wye drops below positive end expiratory pressure (PEEP) minus the operator-set sensitivity level (P_{SENS}). Reference the figure below. As the patient begins the inspiratory effort and breathes gas from the circuit (event 5, the A-B interval in the figure, below), pressure decreases below PEEP. When the pressure drops below PEEP minus P_{SENS} (event 6), the ventilator delivers a PIM breath. The pressure-decline time interval between events A and B determines how aggressive the patient's inspiratory effort is. A short time interval signifies an aggressive breathing effort. The A-B interval is also affected by P_{SENS}. A smaller P_{SENS} setting means a shorter A-B time interval. (The minimum P_{SENS} setting is limited by autotriggering, and the triggering criteria include filtering algorithms that minimize the probability of autotriggering.)

Figure 10-1. Inspiration Using Pressure Sensitivity



1	Exhalation	4	Event B: Patient-triggered inspiration begins
2	Inspiration	5	A-B interval
3	Event A: (patient inspires)	6	Operator-set pressure sensitivity

10.4.2 Flow Triggering

If flow triggering ($\dot{V}_{-TRIG}$) is selected the BDU provides a constant gas flow through the ventilator breathing circuit (called base flow) during exhalation. The base flow is 1.5 L/m greater than the value selected for flow sensitivity ($\dot{V}_{SENS}$). Reference *Inspiration Using Flow Sensitivity*, p. 10-7 where the top graphic represents expiratory flow and the bottom graphic represents inspiratory flow.]

The ventilator's breath delivery flow sensor measures the base flow delivered to the circuit and the exhalation valve flow sensor measures the flow entering the exhalation valve. The ventilator monitors patient flow by measuring the difference between the inspiratory and exhaled flow measurements. If the patient is not inspiring, any difference in measured flows is due to leaks in the breathing system or flow sensor inaccuracy. The clinician can compensate for leaks in the breathing system by increasing $\dot{V}_{SENS}$to a value equal to desired $\dot{V}_{SENS}$ + leak flow.

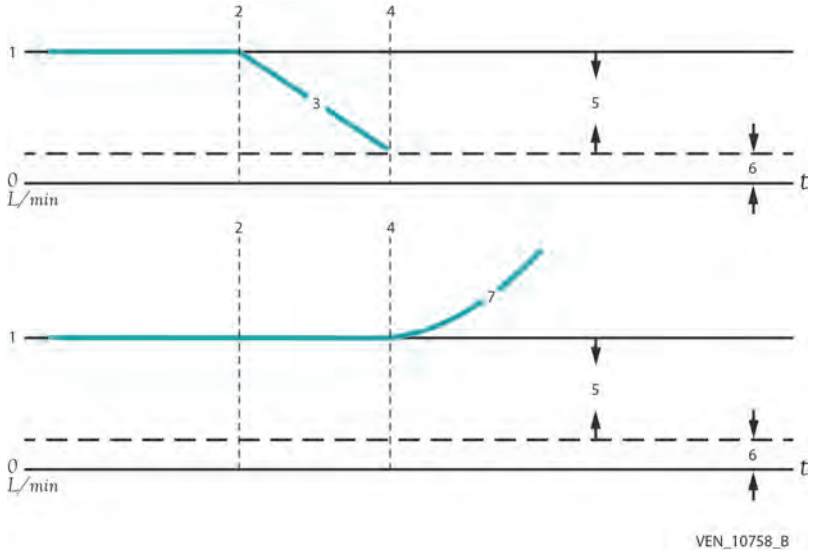
As the patient begins the inspiratory effort and inspires from the base flow, less exhaled flow is measured, while the delivered flow remains constant. Reference the figure below (event A). As the patient continues to inspire, the difference between the delivery and exhalation valve flow sensor measurements increases. The ventilator initiates an inspiration when the difference between the two flow measurements is greater than or equal to the operator-set flow sensitivity value. Reference *Inspiration Using Flow Sensitivity*, p. 10-7, (event B).

As with pressure triggering, the time delay between onset of the patient's effort and actual gas delivery depends on

- How quickly the exhaled flow declines (that is, the aggressiveness of the inspiratory effort). The more aggressive the inspiratory effort, the shorter the interval, and
- the flow sensitivity value. The smaller the value, the shorter the delay

During flow triggering, a backup pressure sensitivity of 2 cmH_2O is present to detect a breath trigger in the event that the flow trigger fails.

Figure 10-2. Inspiration Using Flow Sensitivity

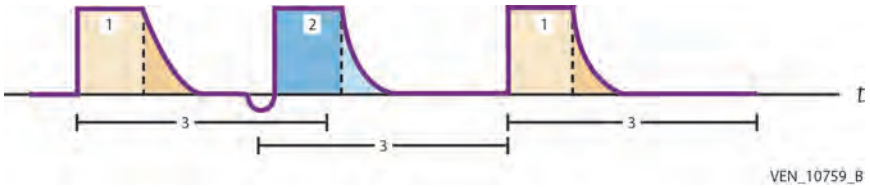


1	Software-set base flow (L/min)	5	Operator-set flow sensitivity
2	Start of patient effort	6	1.5 L/min
3	Event A: flow is decreasing	7	Flow delivered to patient
4	Event B: Gas delivery begins		

10.4.3 Time Triggers

The ventilator measures the time interval for each breath and breath phase. If the ventilator is in Assist/Control (A/C) mode (where the ventilator delivers breaths based on the breath rate setting), a ***VIM*** or ventilator initiated mandatory breath is delivered after the appropriate time interval. The duration of the breath in seconds (Tb) is 60/*f*.

Figure 10-3. Breath Activity During Time-triggered Inspiration



1	Breath activity (VIM)	3	Time period (Tb) = 60/*f*
2	Breath activity (PIM)		

10.4.4 Operator-initiated Triggers

If the operator presses the Manual inspiration key, an ***OIM*** (operator-initiated mandatory) breath is delivered. The ventilator will not deliver an OIM under the following conditions:

- During an active inspiration, whether mandatory or spontaneous
- During the restricted phase of exhalation
- During circuit disconnect and Occlusion Status Cycling (OSC) conditions

Reference *Manual Inspiration*, p. 10-22 later in this chapter for information on the restricted phase of exhalation.

10.4.5 IE Sync Trigger

IE Sync is a software option that allows the ventilator to trigger a breath based on a model of the movement of the patient's respiratory system. Reference *Appendix C* in this manual for a detailed description of the IE Sync option.

10.5 Exhalation — Detection and Initiation

When exhalation occurs, it is called cycling. Mandatory breaths can be volume-cycled or time-cycled by the ventilator or pressure cycled by the patient. Spontaneous breaths can be flow-cycled or pressure-cycled by the patient or time-cycled by the ventilator. A patient-cycled exhalation relies on measurements such as inspiratory flow rate or airway pressure. The ventilator uses the three (3) methods described below to detect exhalation:

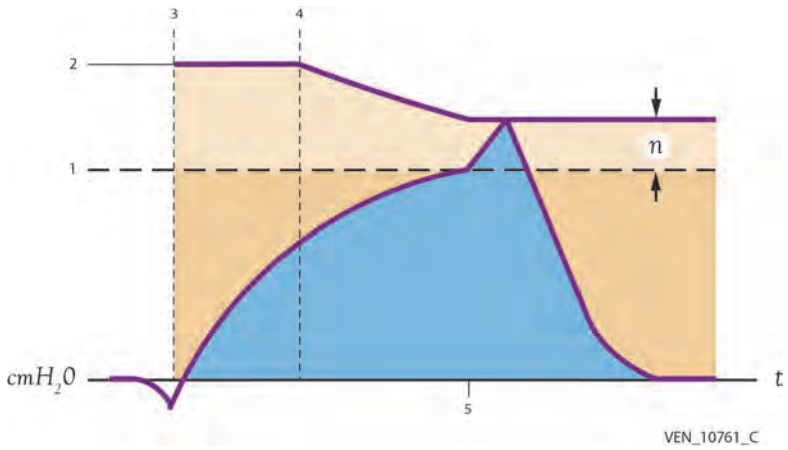
- Airway pressure method (spontaneous breaths)
- Percent peak flow method (spontaneous breaths)
- Time-cycling method (mandatory breaths)
- IE Sync cycled (in SPONT mode only, if the IE Sync option is installed)

10.5.1 Airway Pressure Method

If expiratory sensitivity (E_{SENS}) is set to a value too low for the patient-ventilator combination, a forceful expiratory effort could cause circuit pressure (P_{PEAK}) to rise to its limit. The ventilator monitors circuit pressure throughout the inspiratory phase, and initiates an exhalation when the pressure equals the inspiratory pressure (P_I) target value + an incremental value. This transition to exhalation occurs during spontaneous pressure-based ventilation and in volume support (VS).

Note:
The allowable incremental value above the target pressure is 1.5 cmH_2O once a portion of inspiration time (Tn) has elapsed. Before Tn, the incremental value is higher to allow for transient pressure overshoots. For the first 200 ms of inspiration, the incremental pressure is 10% of the target pressure, up or 8 cmH_2O, whichever is greater. From 200 ms to Tn, the incremental pressure decreases in a linear fashion from the initial value to 1.5 cmH_2O.

Figure 10-4. Exhalation via the Airway Pressure Method



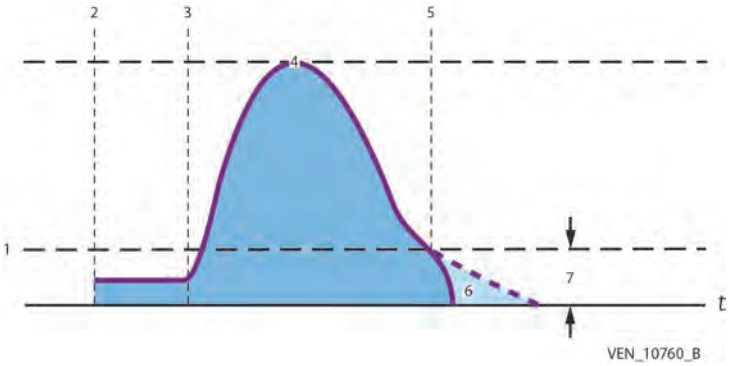
1	Pressure target	4	200 ms
2	Pressure target +incremental value (n)	5	Tn
3	Start breath		

10.5.2 Percent Peak Flow Method

For spontaneous breath types including PS (pressure supported), TC (tube compensated), and VS (volume supported, the ventilator captures the value of the delivered peak inspiratory flow, then monitors the inspiratory flow decline until the value of current flow to peak flow (expressed as a percentage) is less than or equal to the set E_{SENS} value. The ventilator then cycles from inspiration into exhalation.

Reference *Exhalation via the Percent Peak Flow Method*, p. 10-11 for an example of exhalation using this method.

Figure 10-5. Exhalation via the Percent Peak Flow Method



1	Inspiratory flow (0 L/min)	5	Event B: Ventilator initiates exhalation
2	Inspiration	6	Inspiratory flow (L/min) without expiratory trigger
3	Trigger	7	$\dot{V}_{MAX}$ x E_{SENS}/100
4	Event A: delivered flow begins to decrease ($\dot{V}_{MAX}$)		

Note:
PAV+ uses a flow-based cycling method, also called E_{SENS}, but it is expressed in L/min rather than in % of $\dot{V}_{MAX}$.

10.5.3 Time-cycling Method

In pressure ventilation, the set inspiratory time (T_I) defines the duration of the inspiratory phase. In volume ventilation, T_I depends on the tidal volume (V_T) setting, peak flow ($\dot{V}_{MAX}$), flow pattern, and plateau time (T_{PL}). The ventilator cycles into exhalation when the set T_I (pressure ventilation) or computed T_I (volume ventilation) lapses.

10.5.4 IE Sync Cycling

IE Sync detects the end of inspiration when a real-time estimate of the time-derivative of intra-pleural pressure, $\hat{\dot{P}}_P$ (P_{SYNC}), drops below the set E_{SENS} threshold.

10.5.5 Backup Methods

There are four backup methods for preventing excessive duration or pressure during inspiration

- Time limit
- High circuit pressure limit
- High ventilator pressure limit
- High inspired tidal volume limit

10.5.6 Time Limit

For adult and pediatric patients, the time limit method ends inspiration and begins exhalation when the duration of a spontaneous inspiration is greater than or equal to [1.99 s + 0.02 x PBW (kg)] s.

10.5.7 High Circuit Pressure Limit

During any type of inspiration, inspiration ends and exhalation begins when the monitored airway pressure (P_{CIRC}) is greater than or equal to the set high circuit pressure limit.

10.5.8 High Ventilator Pressure Limit

The ventilator transitions from inspiration to exhalation if the high ventilator pressure ($\uparrow P_{VENT}$) limit of 110 cmH_2O is reached.

10.5.9 High Inspired Tidal Volume Limit

The high inspired tidal volume limit terminates inspiration and commences exhalation during VC+, VS, tube compensated (TC), or proportionally assisted (PAV+) breaths if the delivered volume is greater than or equal to $\uparrow V_{TI}$.

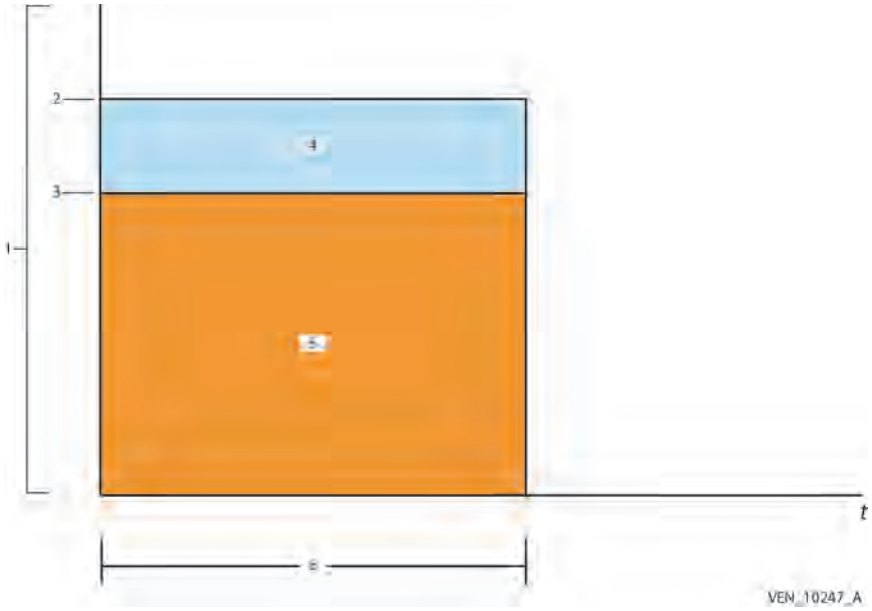
Note:
The ventilator does not generate subatmospheric airway pressures during exhalation.

10.6 Compliance and BTPS Compensation

10.6.1 Compliance Compensation in Volume-based Breaths

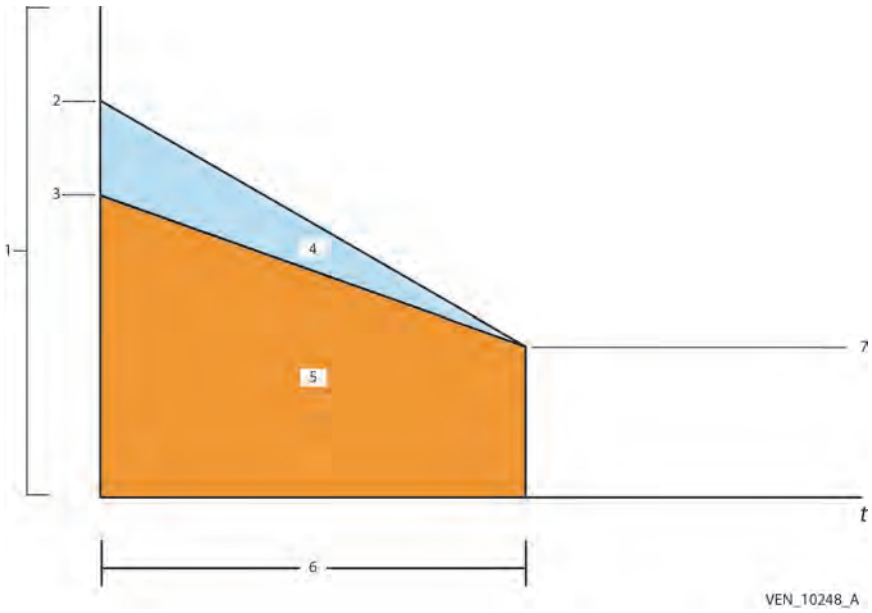
Compliance compensation accounts for the gas volume not actually delivered to the patient during inspiration. This gas is known as the compliance volume, V_C. V_C is the gas lost to pressurizing the breathing circuit and includes the volumes of the patient circuit, any accessories such as a humidifier and water traps, and internal ventilator gas passages.

Figure 10-6. Square Flow Pattern



1	Flow (y-axis)	4	Compliance volume (V_C)
2	Actual $\dot{V}_{MAX}$	5	Set V_T
3	Set $\dot{V}_{MAX}$	6	T_I

Figure 10-7. Descending Ramp Flow Pattern



1	Flow (y-axis)	5	Set V_T
2	Actual $\dot{V}_{MAX}$	6	T_I
3	Set $\dot{V}_{MAX}$	7	Minimum $\dot{V}_{MAX}$
4	Compliance volume (V_C)		

In the ventilator, an iterative algorithm automatically computes the compliance volume. There is a maximum tubing to- patient compliance ratio to reduce the potential for over-inflation due to an erroneous patient compliance estimation. The maximum ratio is determined by the selected patient circuit type and predicted body weight (PBW):

$$Factor = \frac{C_{pt\ ckt}}{C_{pt}}$$

Factor	Compliance volume factor
$C_{pt\ ckt}$	Compliance of the patient circuit
C_{pt}	Compliance of the patient

The compliance volume is calculated as

$$V_C = C_{pt\ ckt}(P_{wye} - P)$$

V_C	Compliance volume	P_{wye}	Pressure at the patient wye at the end of the current inspiration
$C_{pt\ ckt}$	Compliance of the patient circuit	P	Pressure at the end of the current exhalation

Without automated compliance compensation, practitioners would have to compute V_C to estimate the loss of volume in the patient circuit, then increase the V_T setting by that amount. Increasing the tidal volume by a single increment to compensate for compliance volume provides only partial compensation, and requires extra effort and understanding by the practitioner. Additionally, P_{wye} and P can change with time.

An iterative algorithm in the ventilator automatically computes the compliance volume and compensates for it. Compliance compensation does not change inspiratory time (T_I). It is achieved by increasing flow (increasing the amplitude of the selected flow pattern). Keeping T_I constant maintains the original I:E ratio.

There is a maximum compliance volume to reduce the potential for overinflation due to an erroneous compliance volume calculation. The maximum compliance volume is determined by the selected patient circuit type and predicted body weight (PBW), and is summarized by this equation:

$$V_{comp,max} = \text{Factor x Tidal volume}$$

where:

$V_{comp,max}$ = maximum compliance volume

Factor = linear interpolation of the values in the following table for adult, pediatric, and neonatal circuit types. Factor is calculated as:

$$\text{MIN (10, MAX (2.5, 1.0 + (2.0/0.3 x kg PBW)))}$$

Table 10-1. Compliance Volume Factors

Adult patient circuit type		**Pediatric patient circuit type**	
PBW (kg)	**Factor**	**PBW (kg)**	**Factor**
≤ 10	5	≤ 10	5
15	4.6	11	3.5
30	3.4	12.5	2.9
60	2.75	15	2.7
≥ 150	2.5	30	2.5

Note:
Compliance compensation calculations are also in effect during exhalation to ensure spirometry accuracy.

If the patient's compliance decreases beyond the limits of compliance compensation, the ventilator relies on the $\uparrow P_{PEAK}$ alarm setting to truncate the breath and switch to exhalation.

10.6.2 BTPS Compensation in Volume-based Breaths

Volumes and flows are BTPS compensated, that is, they are reported by the ventilator at existing barometric pressure, 37°C (98.6°F), and fully saturated with water vapor.

10.7 Mandatory Breath Delivery

Three mandatory breath types are offered in the ventilator — volume control (VC) which bases breath delivery on the delivered inspiratory tidal volume, pressure control (PC), which bases breath delivery on achieving and sustaining a pressure target for a set period of time, and volume control plus (VC+) which is a pressure-controlled breath based on a target tidal volume. VC+ can be used in situations where a patient's lungs become more compliant due to treatment as it reduces the target pressure (lessening the forces on the alveoli) to achieve the target tidal volume.

Mandatory breaths are delivered by the ventilator, are either assisted (if patient initiated or PIM), or controlled (if ventilator initiated or VIM), or initiated by the operator (OIM). In A/C mode, the breath period (Tb) is calculated using the breath rate (*f*) according to the equation

$$T_b = 60 / f$$

If, during Tb, patient effort is detected, a PIM breath is initiated and a new breath period starts. If no patient effort is detected before Tb lapses, the next breath delivered is a VIM, and a new breath period starts.

Reference *Ventilator Settings Range and Resolution*, p. 11-8 for details on the following VC+ settings:

- Expiratory time (T_E)
- I:E ratio
- Inspiratory time (T_I)

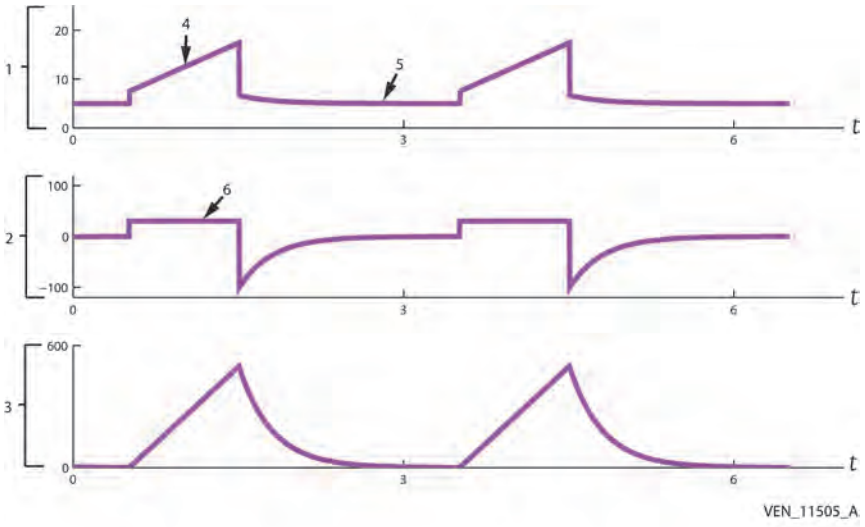
- Rise time %
- Target or tidal volume (V_T)

VC and PC breath types require no initialization. A VC breath is based on meeting a delivered volume target and a PC breath is based on meeting a specific pressure target. VC+ breaths, however, go through a startup routine.

10.7.1 Volume Control (VC)

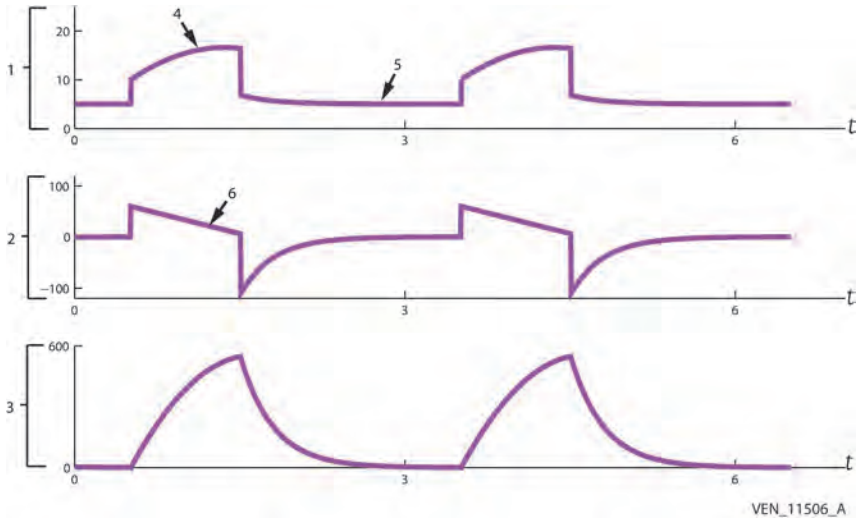
Volume Control is the control scheme that controls the flow with for the purpose of supplying a predetermined volume (set by the practitioner) to the patient. There are two basic flow wave forms to administer this volume: the "square" that guarantees a constant flow during the inspiration time, or the "descending ramp" whose slope and initial value are determined to provide the required volume target. Reference *Ideal Waveform Using Square Flow Pattern*and *Ideal Waveform Using Descending Ramp Flow Pattern*. The inspiration time is determined indirectly by the characteristics of the selected flow wave.

Figure 10-8. Ideal Waveform Using Square Flow Pattern



1	Pressure (cmH_2O)	4	Inspiration phase
2	Flow (L/min)	5	Expiration phase
3	Volume (mL)	6	Constant flow

Figure 10-9. Ideal Waveform Using Descending Ramp Flow Pattern

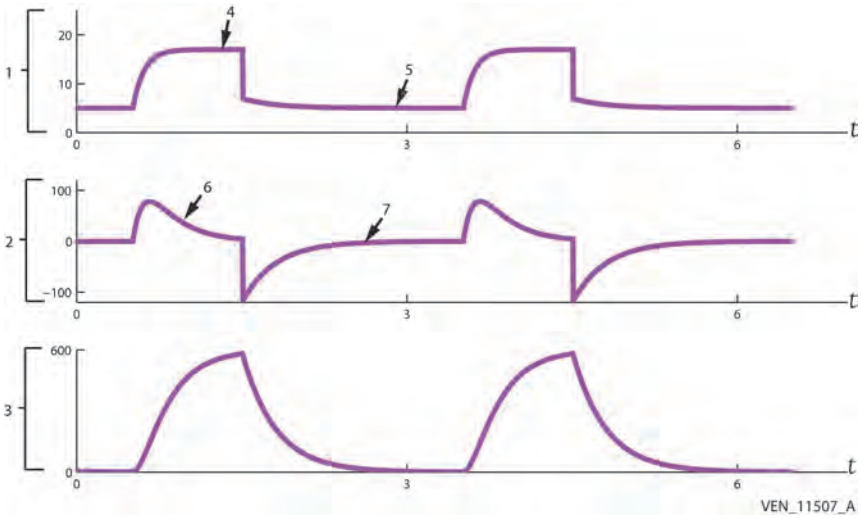


1	Pressure (cmH_2O)	4	Inspiration phase
2	Flow (L/min)	5	Expiration phase
3	Volume (mL)	6	Descending ramp

10.7.2 Pressure Control (PC)

Pressure Control is the control scheme by which the pressure is controlled at the circuit wye to reach a constant level (set by the practitioner) during inspiration, and a PEEP level during exhalation. Reference *Ideal Waveform Using Pressure Control Ventilation* on *page 10-20*. This level is maintained for a time given by the set inspiration time, following followed by an exhalation regulated by the exhalation valve until the PEEP level is reached. As flow is not predetermined, the supplied volume varies depending on the patient's pulmonary response.

Figure 10-10. Ideal Waveform Using Pressure Control Ventilation



1	Pressure (cmH_2O)	5	PEEP
2	Flow (L/min)	6	Inspiration phase
3	Volume (mL)	7	Expiration phase
4	Target pressure		

10.7.3 VC+

VC+ breaths require initialization and must go through a startup routine.

VC+ Startup

During VC+ startup, the ventilator delivers at least one breath (test breath) to determine the pressure target needed to deliver the desired (set) volume. During the time the ventilator is delivering the test breaths, the message "VC+ startup" is displayed in the GUI's prompt area.

Note:
To allow for optimal function of startup and operation of VC+ in the ventilator it is important not to block the tubing while the patient is undergoing suctioning or other treatment that requires disconnection from the ventilator. The ventilator has a disconnect detection algorithm that suspends ventilation while the patient is disconnected.

After VC+ Startup, the ventilator will make adjustments to the target pressure in order to deliver the set volume (V_T). In order to reach the desired volume promptly, the maximum allowed pressure adjustments for an Adult or Pediatric patient will be greatest during the first five breaths following Startup or a change in V_T or $V_{T\ SUPP}$. The values of the maximum pressure adjustments for each patient type are summarized below.

Table 10-2. Maximum Pressure Adjustments

Conditions	Maximum change in target pressure		
	PBW ≥ 25 kg	**15 ≤ PBW < 25 kg**	**PBW < 15 kg**
Less than five breaths after: VC+ startup or Change in V_T	± 10.0 cmH_2O	± 6.0 cmH_2O	± 3.0 cmH_2O
Five breaths or more after VC+ startup	± 3.0 cmH_2O	± 3.0 cmH_2O	± 3.0 cmH_2O

Reference *Non-technical Alarm Summary*, p. 6-18 for details on the following VC+ alarms:

- VOLUME NOT DELIVERED
- HIGH INSPIRED TIDAL VOLUME (↑V_{TI})
- LOW CIRCUIT PRESSURE (↓P_{PEAK})
- COMPLIANCE LIMITED V_T

During VC+, inspiratory target pressure cannot be lower than PEEP + 3 cmH_2O and cannot exceed P_{PEAK} - 3 cmH_2O.

10.7.4 Rise time %

If PC or VC+ is selected as the Mandatory type, adjust rise time % for optimum flow delivery into the lungs. Patients with high impedance (low compliance, high resistance) may benefit from a lower rise time% whereas patients with low impedance may better tolerate a more aggressive rise time setting. The rise time % setting specifies the speed at which the inspiratory pressure reaches

95% of the target pressure. The rise time setting applies to PS (including a setting of 0 cmH_2O), PC, or VC+ breaths. To match the flow demand of an actively breathing patient, observe simultaneous pressure-time and flow-time curves, and adjust the rise time % to maintain a smooth rise of pressure to the target value. A rise time % setting reaching the target value well before the end of inspiration can cause the ventilator to supply excess flow to the patient. Whether this oversupply is clinically beneficial must be evaluated for each patient. Generally, the optimum rise time % for gently breathing patients is less than or equal to the default (50%), while optimum rise time % for more aggressively breathing patients can be 50% or higher.

WARNING:
Under certain clinical circumstances (such as stiff lungs, or a small patient with a weak inspiratory drive), a rise time % setting above 50% could cause a transient pressure overshoot and premature transition to exhalation, or pressure oscillations during inspiration. Carefully evaluate the patient's condition before setting the rise time % above the default setting of 50%.

10.7.5 Manual Inspiration

When pressed, the Manual Inspiration key delivers one OIM breath to the patient, using set breath delivery parameters. The ventilator will not allow a manual inspiration during the restricted phase of exhalation or when the ventilator is in the process of delivering a breath (whether mandatory or spontaneous). All manual inspiration attempts are logged in the General Event log.

The ***restricted phase of exhalation*** is the time period during the exhalation phase where an inspiration trigger is not allowed. The restricted phase of exhalation is defined as the first 200 ms of exhalation OR the time it takes for expiratory flow to drop to ≤ 50% of the peak expiratory flow, OR the time it takes for the expiratory flow to drop to ≤ 0.5 L/min (whichever is longest). The restricted phase of exhalation will end after five (5) *s* of exhalation have elapsed regardless of the measured expiratory flow rate.

10.8 Spontaneous Breath Delivery

The modes allowing spontaneous breaths are SIMV, SPONT, and BiLevel.

The spontaneous breath type setting determines which type of pressure-assist will be applied to the patient's spontaneous breaths (PS, TC, VS, or PAV+).

After selecting the spontaneous breath type, choose the level of pressure support (P_{SUPP}) for PS, Support volume ($V_{T\ SUPP}$) for VS or percent support for TC and PAV+ (if the PAV+ option is installed) and specify the rise time % and E_{SENS}, where available. Changes to the spontaneous breath type setting phase in at the start of the next inspiration.

Note:
In any delivered spontaneous breath, either INVASIVE or NIV, there is always a target inspiratory pressure of at least 1.5 cmH_2O applied.

During spontaneous breathing, the patient's respiratory control center rhythmically activates the inspiratory muscles. The support type setting allows selection of pressure-assist to supplement the patient's pressure-generating capability.

Table 10-3. Spontaneous Breath Delivery Characteristics

Characteristic	Implementation
Inspiratory detection	P_{SENS}, $\dot{V}_{SENS}$, or IE Sync depending on the trigger type selected.
Pressure or flow during inspiration Spontaneous type = PS and $P_{SUPP} < 5$ cmH_2O	Pressure rises according to the selected rise time % and PBW setting, with target pressure equal to the effective pressure + PEEP: P_{SUPP} Effective pressure (cmH_2O) 0 1.5 1 2.2 2 2.9 3 3.6 4 4.3
Pressure or flow during inspiration Spontaneous type = PS and $P_{SUPP} \geq 5$ cmH_2O	Pressure rises according to the selected rise time % and PBW setting, and target pressure equals P_{SUPP} + PEEP.
Pressure or flow during inspiration Spontaneous type = VS	Pressure rises according to the selected rise time % and PBW setting, and target pressure equals the pressure determined during the test breath or pressure target determined from assessment of delivered volume from the previous breath. For more information on VS,Reference *Volume Support (VS)*, p. 10-25.

Table 10-3. Spontaneous Breath Delivery Characteristics (Continued)

Characteristic	Implementation
Tube Compensation (TC)	Tube Compensation provides programmable, inspiratory pressure assistance during otherwise unsupported spontaneous breaths. This assists the patient in overcoming the flow resistance of the artificial airway. Pressure is programmed to help the patient overcome part or all of the resistance of the artificial airway. The ventilator continuously calculates the pressure differential based on tube type and tube ID and adjusts the compensation pressure accordingly. For more information regarding TC, Reference *Tube Compensation*, p. 10-27.
Inspiratory flow profile	The inspiratory flow profile is determined by patient demand and the rise time % setting. As the rise time % setting is increased from minimum to maximum, the time to achieve the pressure target decreases. The maximum available flow is up to 30 L/min for neonatal circuit types, 80 L/min for pediatric circuit types, and up to 200 L/min for adult circuit types without Leak Sync.
Exhalation valve during inspiration	Adjusts to minimize pressure overshoot and maintain the target pressure.
Inspiratory valve during inspiration	Adjust to maintain target pressure. Because the exhalation valve acts as a relief valve venting any excess flow, inspiratory flow can be delivered aggressively and allows reduced work of breathing.
Expiratory detection	The end-inspiratory flow or airway pressure method or IE Sync cycling (if IE Sync is installed), whichever detects exhalation first. Time backup and the $\uparrow P_{PEAK}$ alarm are also available as backup strategies.
Pressure or flow during exhalation	Pressure is controlled to PEEP. For pressure triggering: set to deliver a bias flow of 1 L/min near the end of expiratory flow. For flow triggering: set to deliver base flow.
Inspiratory valves during exhalation	For pressure triggering: set to deliver a bias flow of 1 L/min near the end of expiratory flow. For flow triggering: set to deliver base flow near the end of expiratory flow.
Exhalation valve during exhalation	Adjusts to maintain the operator-selected value for PEEP.

10.8.1 Pressure Support (PS)

Pressure Support is a type of spontaneous breath, similar to PC, by which the pressure is controlled to reach a constant value, preset by the practitioner, once an inspiratory effort is detected. This target value is held until the detection of end of inspiration. Subsequently, the exhalation valve control initiates the exhalation, driving the pressure to the PEEP level.

10.8.2 Volume Support (VS)

Volume support is a pressure-supported spontaneous breath type available when SPONT is selected as the mode. The target support volume ($V_{T\ SUPP}$) is the target volume for pressure supported breaths.

Reference *Ventilator Settings Range and Resolution*, p. 11-8 for details regarding the following VS settings:

- Expiratory sensitivity (E_{SENS})
- Rise time %
- Target support volume ($V_{T\ SUPP}$)

Technical Description

Volume Support (VS) breaths are patient-triggered, pressure-supported spontaneous breaths. The VS algorithm varies the inspiratory pressure of each breath to deliver the operator-set target tidal volume ($V_{T\ SUPP}$). If the delivered volume for a breath is above or below the set target volume, VS adjusts the target pressure for the next breath up or down, as necessary, to deliver more or less volume. As the patient's condition improves allowing more patient control over spontaneous ventilation, the VS algorithm decreases the amount of inspiratory pressure necessary to deliver the target volume. Conversely, VS increases inspiratory pressure if the patient's respiratory drive becomes compromised.

In the absence of leaks or changes in patient resistance or compliance, Volume Support achieves and maintains a steady, breath-to-breath tidal volume within five (5) breaths of VS initiation or startup.

During VS, the inspiratory pressure target cannot be lower than PEEP + 1.5 cmH_2O, and cannot exceed P_{PEAK} - 3 cmH_2O.

VS Startup

During startup, the ventilator delivers a breath (test breath) to determine the pressure target needed to deliver the desired (set) volume. During the time the ventilator is delivering the test breath, the message "VS startup" is displayed in the GUI's prompt area.

Test breaths are defined as:

A PS spontaneous breath with P_{SUPP} = the lesser of 15 cmH_2O and (P_{PEAK}-PEEP-3) cmH_2O

Note:
To allow for optimal function of startup and operation of VS in the ventilator it is important not to block the tubing while the patient is undergoing suctioning or other treatment that requires disconnection from the ventilator. The ventilator has a disconnect detection algorithm that suspends ventilation while the patient is disconnected.

After VS Startup, the ventilator makes adjustments to the target pressure in order to deliver the set volume ($V_{T\ SUPP}$). In order to reach the desired volume promptly, the maximum allowed pressure adjustments for an Adult or Pediatric patient will be greatest during the first five breaths following Startup or a change in $V_{T\ SUPP}$. The values of the maximum pressure adjustments for each patient type are summarized in the table below.

Table 10-4. Maximum Pressure Adjustments

Conditions	Maximum change in target pressure		
	PBW ≥ 25 kg	**15 kg ≤ PBW < 25 kg**	**PBW < 15 kg**
Less than five breaths after: VS startup or Change in $V_{T\ SUPP}$	± 10.0 cmH_2O	± 6.0 cmH_2O	± 3.0 cmH_2O
Five breaths or more after VS startup	± 3.0 cmH_2O	± 3.0 cmH_2O	± 3.0 cmH_2O

Reference *Non-technical Alarm Summary*, p. 6-18 for details on the following VS alarms:

- VOLUME NOT DELIVERED
- COMPLIANCE LIMITED V_T
- HIGH INSPIRED TIDAL VOLUME (↑V_{TI})

Monitored Patient Data

Reference *Patient Data Range and Resolution*, p. 11-19 for details on the Spontaneous inspired tidal volume patient data parameter available during VS breaths.

10.8.3 Tube Compensation

Tube Compensation (TC) is a pressure-supported spontaneous breath type available in SIMV, SPONT and BiLevel modes. When TC is enabled, the patient's respiratory muscles are not required to work as hard to draw gases into the lungs as they would in the absence of the pressure assistance provided by the TC feature. This is particularly important for patients whose respiratory systems are already functioning poorly, and would have to exert even greater muscular effort to overcome the increased resistance to flow through the artificial airway.

Tube Compensation provides programmable, inspiratory pressure assistance during otherwise unsupported spontaneous breaths. This assists the patient in overcoming the flow resistance of the artificial airway. Pressure is programmed to vary in accordance with the resistance to flow of the artificial airway. The ventilator continuously calculates the pressure differential and adjusts the compensation pressure accordingly.

Tube Compensation also includes safety protection, safety checks, and logic checks which prevent the operator from entering certain incompatible settings, such as a large airway size paired with a small predicted body weight.

If the type of humidifier has been changed after running SST with TC, the volume can be adjusted at the same time to avoid a reduction in compensation compliance accuracy.

Technical Description

Tube Compensation is a spontaneous mode enhancement which assists patients' spontaneous breaths not already supported by specific pressure-based breath types (such as PS, VS, and PAV+) by delivering positive pressure proportional to the flow-based, resistive pressure developed across the artificial airway. TC causes the sensation of breathing through an artificial airway to diminish because the TC algorithm instructs the ventilator to develop just the correct amount of forward pressure to offset (cancel) the back pressure developed across the artificial airway during the inspiratory phase. The degree

of cancellation can be set by the clinician and is adjustable between 10% an 100% in increments of 5%.

Tube Compensation can support all unsupported spontaneous breaths for patients with predicted body weights ≥ 7.0 kg (15.4 lb), and for endotracheal/tracheostomy tubes with an inside diameter (ID) of ≥ 4.5 mm. TC can be used within SPONT, BiLevel (if this option is installed) or SIMV, all of which permit unsupported spontaneous breaths. With BiLevel selected, TC supports spontaneous breaths at both pressure levels.

Tube Compensation checks the flow rate every 5 *ms*, using an internal lookup table which contains the flow-to-pressure relationship of the selected artificial airway, and is used to calculate the amount of pressure needed to overcome all or part of the resistance of the artificial airway. Based on the TC setting and the instantaneous flow measurement, the ventilator's PSOL valves are continually adjusted, adjusting the circuit pressure to match the changing tube-pressure compensation requirements.

Tube Compensation Alarms

Reference *Non-technical Alarm Summary*, p. 6-18 for details of the ↑P_{COMP}, ↑P_{VENT}, and ↑V_{TI} alarms associated with TC.

Monitored Patient Data

Reference *Patient Data Range and Resolution*, p. 11-19 for details of the inspired tidal volume (V_{TI}) monitored patient data parameter a associated with TC.

Tube Inside Diameter (ID)

The ventilator uses "soft bound" and "hard bound values for estimated tube inside diameter (ID) based on PBW. Soft bounds are ventilator settings that have reached their recommended high or low limits. When adjusting the tube size, if the inside diameter does not align with a valid predicted body weight, a *Continue* button appears. Setting the ventilator beyond these soft bounds requires the operator to acknowledge the prompt by touching the *Continue* button before continuing to adjust the tube size.The limit beyond which the tube ID cannot be adjusted is called a hard bound, and the ventilator emits an invalid entry tone when a hard bound is reached.

WARNING:
Greater than expected ventilatory support, leading to unknown harm, can result if the specified tube type or tube ID is smaller than the actual tube type or tube ID.

Ventilator Settings/Guidelines

The estimation of settings to use with TC is aided by an understanding of: the ventilator settings, the data used for determination of the compensation values, and the specified performance or accuracy of the TC function.

The setting for $\overline{\uparrow}P_{PEAK}$ must take the estimated tube compensation into consideration. The target pressure (compensation) at the patient wye is derived from the knowledge of the approximate airway resistance of the ET or tracheostomy tube being used. The compensation pressure in cmH_2O for available tube sizes and gas flows is shown. Reference *ET Tube Target Pressure vs. Flow*, p. 10-30 and Reference *Tracheostomy Tube Target Pressure vs. Flow*, p. 10-31. The estimated compensation must be added to the value of PEEP for calculation and setting of $\overline{\uparrow}P_{PEAK}$.

Specified Performance

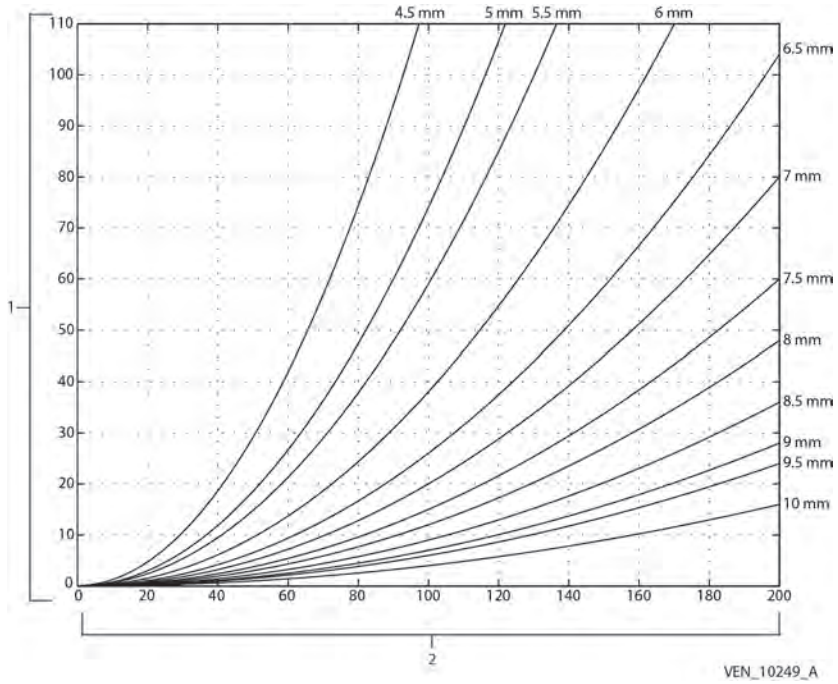
Performance using TC is specified to be ± (0.5 + 10% of actual) joules/liter (residual work during inspiration at the 100% support (% Supp) level). Work is computed over the entire inspiratory interval.

$$W = \frac{k \times \int (P_{E\ END} - P_{TR}) \times \dot{V}\, dt}{\dot{V}\, dt}$$

W	Work [J/L]	P_{TR}	Tracheal pressure
$P_{E\ END}$	End expiratory pressure	k	Conversion constant (0.098) [J/cmH_2O x L)

The following figures indicate pressures at steady-state flows for ET tubes and tracheostomy tubes, respectively, at 100% support at the wye for sizes between 4.5 mm and 10 mm.

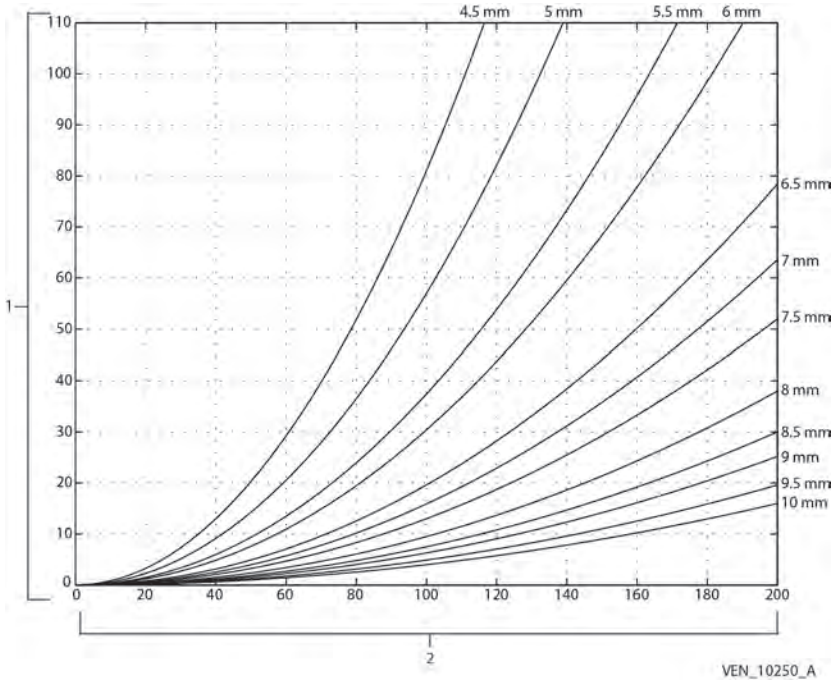
Figure 10-11. ET Tube Target Pressure vs. Flow



1 Pressure (cmH_2O)

2 Flow (L/min)

Figure 10-12. Tracheostomy Tube Target Pressure vs. Flow



1 Pressure (cmH_2O) 2 Flow (L/min)

10.8.4 Proportional Assist Ventilation (PAV™+)

PAV+ is another type of spontaneous breath, which is available only if the PAV+ option is installed. For detailed description of the operating theory, reference *Appendix D* in this manual.

10.9 A/C Mode

When the ventilator is in ***assist-control (A/C)*** mode, only mandatory breaths are delivered. These mandatory breaths can be PC, VC, or VC+ breaths. Reference *Mandatory Breath Delivery*, p. 10-17 for a more detailed explanation of VC+ breaths. As for any mandatory breath, the triggering methods can be P_{-TRIG}, $\dot{V}_{-TRIG}$, time-triggered, or operator initiated. If the ventilator senses the patient initiating the breath, a PIM or ***assist breath*** is delivered. Otherwise, VIM breaths (***control breaths***) are delivered based on the set respiratory rate. The length of the breath period is defined as

where:

$$Tb = 60 / f$$

Tb = breath period (s)

f = set respiratory rate (breaths per minute)

The inspiratory phase length is determined by the current breath delivery settings. At the end of the inspiratory phase, the ventilator enters the expiratory phase as determined by the following equation:

$$T_E = Tb - T_I$$

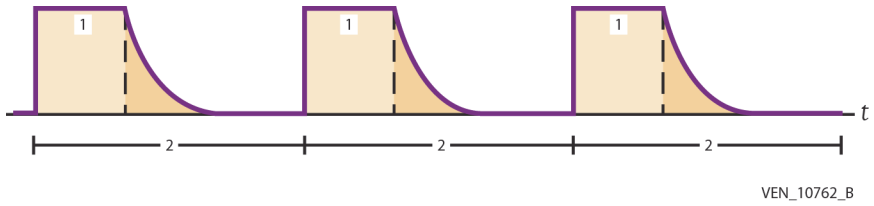
where:

T_E = length of the expiratory phase (s)

T_I = length of inspiratory phase(s) including plateau time, T_{PL}

The figure shown below illustrates A/C breath delivery when there is no patient inspiratory effort detected (all inspirations are VIMs).

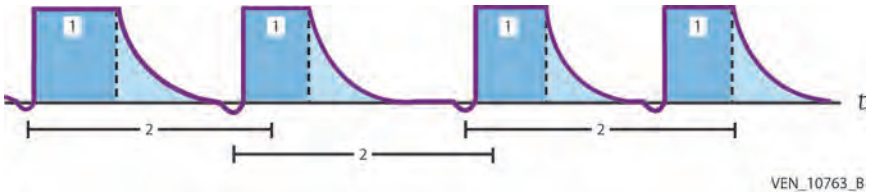
Figure 10-13. No Patient Inspiratory Effort Detected



1 VIM 2 Tb

The figure below shows A/C breath delivery when patient inspiratory effort is detected. The ventilator allows PIM breaths to be delivered at a rate greater than or equal to the set respiratory rate.

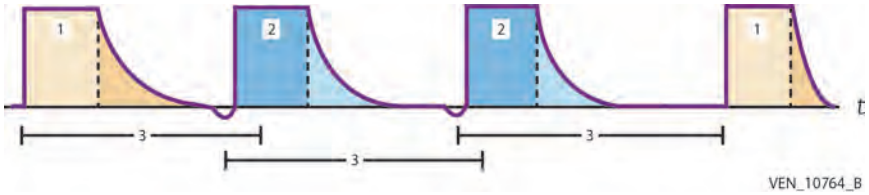
Figure 10-14. Patient Inspiratory Effort Detected



1 PIM 2 Tb set

The figure shown below illustrates A/C breath delivery when there are both PIM and VIM breaths. delivered.

Figure 10-15. Combined VIM and PIM Breaths



1 VIM 3 Tb set

2 PIM

If changes to the respiratory rate are made, they are phased in during exhalation only. The new breath period depends on the new respiratory rate, is based on the start of the current breath, and follows these rules

- The current breath's inspiratory time is not changed.
- A new inspiration is not delivered until at least 200 ms of exhalation have elapsed.
- The maximum time t until the first VIM for the new respiratory rate is delivered is 3.5 times the current inspiratory time or the length of the new breath period (whichever is longer), but t is no longer than the old breath period.
- If the patient generates a PIM after the ventilator recognizes the rate change and before time t, the new rate begins with the PIM.

10.9.1 Changing to A/C Mode

Switching to A/C mode from any other mode causes the ventilator to phase in a VIM and set the start time for the beginning of the next A/C breath period. Following this VIM, and before the next A/C period begins, the ventilator responds to the patient's inspiratory efforts by delivering mandatory breaths.

The first A/C breath (VIM breath) is phased in while following these rules

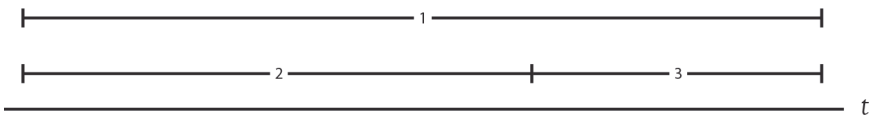
- The breath is not delivered during an inspiration.
- The breath is not delivered during the restricted phase of exhalation.
- The ventilator ensures the apnea interval elapses at least five (5) *s* after the beginning of exhalation.
- Any other specially scheduled event (for example, a respiratory mechanics maneuver or any pause maneuver) is canceled and rescheduled at the next interval.

When the first VIM of the new A/C mode is delivered depends on the mode and breath type active when the mode change is requested.

10.10 SIMV Mode

Synchronous Intermittent Mandatory Ventilation (SIMV) mode is a mixed ventilation mode allowing both mandatory and spontaneous breaths using pressure- or flow-triggering. The mandatory breaths can be PC, VC, or VC+, and the spontaneous breaths are pressure-assisted with either PS or TC. SIMV guarantees one mandatory breath per SIMV breath period, which is either a PIM or VIM. OIM breaths are allowed in SIMV and are delivered at the setting selected for Mandatory Type. Reference the figure below which shows the two parts of the SIMV breath period.

Figure 10-16. Mandatory and Spontaneous Intervals



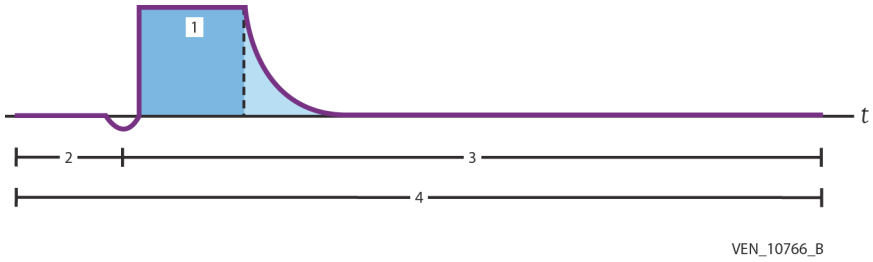
1 Tb = SIMV breath period (includes T_m and T_s

2 Tm = Mandatory interval (reserved for a PIM breath)

3 Ts = Spontaneous interval (VIM delivered if no PIM delivered during Tm

The first part of the period is the mandatory interval (T_m) which is reserved for a PIM. If a PIM is delivered, the T_m interval ends and the ventilator switches to the second part of the period, the spontaneous interval (T_s), which is reserved for spontaneous breathing for the remainder of the breath period. At the end of an SIMV breath period, the cycle repeats. If a PIM is not delivered during the mandatory interval, the ventilator delivers a VIM at the end of the mandatory interval, then switches to the spontaneous interval. The following figure shows an SIMV breath period where a PIM is delivered within the mandatory interval. Any subsequent trigger efforts during T_s yield spontaneous breaths. As shown, T_m transitions to T_s when a PIM is delivered.

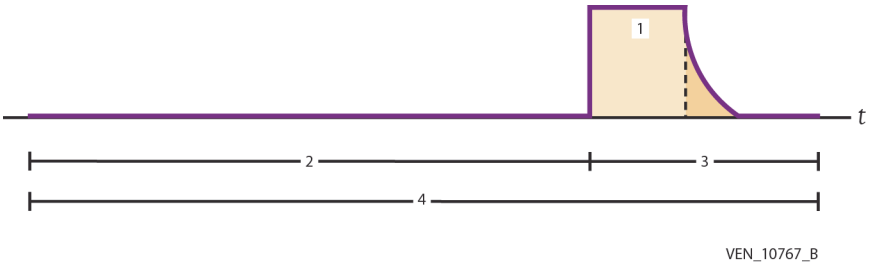
Figure 10-17. PIM Delivered Within Mandatory Interval



1	PIM	3	Ts (subsequent trigger efforts during Ts yield spontaneous breaths)
2	Tm (Tm transitions to Ts when a PIM is delivered)	4	Tb

The following figure shows an SIMV breath period where a PIM is not delivered within the mandatory interval.

Figure 10-18. PIM *Not* Delivered Within Mandatory Interval



1	VIM	3	Ts

2	Tm (VIM delivered at end of Tm if no PIM delivered during Tm	4	Tb

In SIMV, mandatory breaths are identical to those in A/C mode if the ventilator's respiratory rate setting is greater than the patient's natural respiratory rate. Spontaneous breaths are identical to those in SPONT mode if the ventilator setting for respiratory rate is significantly below the patient's natural respiratory rate. Patient triggering must meet the requirements for pressure and flow sensitivity.

The procedure for setting the respiratory rate in SIMV is the same as in A/C mode. Once the respiratory rate (*f*) is set, the SIMV interval period Tb in seconds is

$$Tb = 60 / f$$

During the mandatory interval, if the patient triggers a breath according to the current setting for pressure or flow sensitivity, the ventilator delivers a PIM. Once a mandatory breath is triggered, T_m ends, T_s begins, and any further trigger efforts yield spontaneous breaths. During the spontaneous interval, the patient can take as many spontaneous breaths as allowed. If no PIM or OIM is delivered by the end of the mandatory interval, the ventilator delivers a VIM and transitions to the spontaneous interval at the beginning of the VIM.

The SIMV breathing algorithm delivers one mandatory breath each period interval, regardless of the patient's ability to breathe spontaneously. Once a PIM or VIM is delivered, all successful patient efforts yield spontaneous breaths until the cycle interval ends. The ventilator delivers one mandatory breath during the mandatory interval, regardless of the number of successful patient efforts detected during the spontaneous interval. (An OIM delivered during the mandatory interval satisfies the mandatory breath requirement, and causes T_m to transition to T_s.)

The maximum mandatory interval for any valid respiratory rate setting in SIMV is defined as the lesser of

- 0.6 x the SIMV interval period (Tb), or
- ten *s*.

There is no minimum value for T_m.

In SIMV, the interval from mandatory breath to mandatory breath can be as long as 1.6 x the SIMV period interval (but no longer than the period interval

+ ten (10) *s*. At high respiratory rates and too-large tidal volumes, ***breath stacking*** (the delivery of a second inspiration before the first exhalation is complete) is likely. In volume ventilation, breath stacking during inspiration and early exhalation leads to hyperinflation and increased airway and lung pressures, which can be detected by a high pressure limit alarm. In pressure control ventilation (with inspiratory pressure remaining constant), breath stacking leads to reduced tidal volumes, which can be detected by the low tidal volume and minute ventilation alarms.

In SIMV mode it is possible for the respiratory rate to drop temporarily below the *f* setting (unlike A/C mode, in which f_{TOT} is always greater than or equal to the *f* setting). If the patient triggers a breath at the beginning of a breath period, then does not trigger another breath until the maximum mandatory interval for the following breath has elapsed, a monitored respiratory rate less than the respiratory rate setting can result.

If a spontaneous breath occurs toward the end of the spontaneous interval, inspiration or exhalation can still be in progress when the SIMV interval ends. No VIM, PIM, or OIM is allowed during the restricted phase of exhalation. In the extreme, one or more expected mandatory breaths could be omitted. When the expiratory phase of the spontaneous breath ends, the ventilator reverts to its normal criteria for delivering mandatory breaths.

If an OIM is detected during the mandatory interval, the ventilator delivers the currently specified mandatory breath then closes T_m and transitions to T_s. If an OIM is detected during the spontaneous interval, the ventilator delivers the currently specified mandatory breath, but the SIMV cycle timing does not restart if OIM breaths are delivered during T_s.

10.10.1 Changing to SIMV Mode

Switching the ventilator to SIMV from any other mode, causes the ventilator to phase in a VIM and set the start time for the next SIMV period. Following this VIM, but before the next SIMV period begins, the ventilator responds to successful patient inspiratory efforts by delivering spontaneous breaths. The first SIMV VIM breath is phased in according to the following rules:

- The VIM breath is not delivered during an inspiration or during the restricted phase of exhalation.
- If the current mode is A/C, the first SIMV VIM is delivered after the restricted phase of exhalation plus the shortest of the following intervals, referenced to the beginning of the last or current inspiration: 3.5 T_I, current T_A, or the length of the current breath period.

- If the current mode is SPONT, and the current or last breath type was spontaneous or OIM, the first SIMV VIM is delivered after the restricted phase of exhalation plus the shortest of the following intervals, referenced to the beginning of the last or current inspiration: 3.5 x T_I, or current T_A.

- If the current mode is BiLevel in the P_H state and the current breath is mandatory, the PEEP level will be reduced to P_L once the exhalation phase is detected

The time *t* until the first VIM of the new A/C mode is the lesser of:

  – PEEP transition time + 2.5 x duration of the active gas delivery phase, or

  – the length of the apnea interval (T_A), or

  – the length of the current breath cycle

- If the current mode is BiLevel in the P_H state and the current breath is spontaneous:

  – the PEEP level will be reduced once the exhalation phase is detected

The time *t* until the first VIM of the new A/C mode is the lesser of:

  – PEEP transition time + 2.5 x duration of the spontaneous inspiration, or

  – the start time of the spontaneous breath + the length of the apnea interval (T_A).

- If the current mode is BiLevel in the P_L state and the current breath is mandatory, the time *t* until the first VIM of the new A/C mode is the lesser of:

  – PEEP transition time + 2.5 x duration of the active gas delivery phase, or

  – the length of the apnea interval (T_A), or

  – the length of the current breath cycle

- If the current mode is BiLevel in the P_L state and the current breath is spontaneous and the spontaneous start time has occurred during P_L, the time *t* until the first VIM of the new A/C mode is the lesser of:

  – 3.5 x duration of the spontaneous inspiration, or

  – the length of the apnea interval (T_A) or

  – the length of the current breath cycle

- If the current mode is BiLevel in the P_L state and the current breath is spontaneous and the spontaneous start time has occurred during P_H, the time *t* until the first VIM of the new A/C mode is the lesser of:
  - PEEP transition time + 2.5 x duration of the spontaneous inspiration, or
  - the start time of the spontaneous breath + the length of the apnea interval (T_A).

If the command to change to SIMV occurs after the restricted phase of exhalation has ended, and before a next breath or the apnea interval has elapsed, the ventilator delivers the first SIMV VIM at the moment the command is recognized.

The point at which the new rate is phased in depends on the current phase of the SIMV interval and when the rate change command is accepted. If the rate change occurs during the mandatory interval, the maximum mandatory interval is that for the new or old rate, whichever is less. If the patient generates a successful inspiratory effort during the spontaneous interval, the ventilator responds by delivering a spontaneous breath.

Respiratory rate changes are phased in during exhalation only. The new SIMV interval is determined by the new respiratory rate and is referenced to the start of the current SIMV period interval, following these rules:

- Inspiratory time (T_I) of current breath is neither truncated nor extended.
- The new inspiration is not delivered until 200 ms of exhalation have elapsed.

The time until the new SIMV interval begins is

- whichever is greater: the new SIMV period interval or 3.5 x the last or current T_I,
- but not greater than the current SIMV period interval.

10.11 Spontaneous (SPONT) Mode

In SPONT mode, the patient initiates inspiration according to the trigger type in effect, but OIM breaths are allowed which are delivered with the currently specified mandatory breath parameters. The following spontaneous breath types are available in SPONT mode:

- PS
- VS
- TC

- PAV+ (if the PAV+™ option is installed)

The inspiratory phase begins when the ventilator detects patient effort during the ventilator's exhalation phase. Breath delivery during the inspiratory phase is determined by the settings for pressure support, PEEP, rise time%, and expiratory sensitivity, unless the breath is an OIM breath.

If Tube Compensation (TC), or Proportional Assist Ventilation (PAV+) (if the PAV+, option is installed) is selected as the spontaneous type, breath delivery during the inspiratory phase is determined by the settings for% support (% Supp), expiratory sensitivity, tube ID, and tube type.

Note:
Given the current ventilator settings, if PAV+ would be an allowable spontaneous type (except that tube ID < 6 mm) then PAV+ becomes selectable. If selected, tube ID is set to its New Patient default value based on the PBW entered. An attention icon for tube ID appears.

If Volume Support (VS) is selected as the spontaneous type, breath delivery during the inspiratory phase is determined by rise time %, volume support level ($V_{T\ SUPP}$), expiratory sensitivity, and PEEP.

Inspiratory pauses are only possible during OIM breaths, and expiratory pauses are not allowed during SPONT.

Expiratory trigger methods include:

- E_{SENS} (% flow deceleration from peak inspiratory flow)
- PBW based time limit (T_I too long)
- $\uparrow P_{PEAK}$
- Inspiratory tidal volume limit (for VS only)
- IE Sync (if the IE Sync option is installed)
- Airway Pressure Cycling method

10.11.1 Changing to SPONT Mode

If the operator changes to SPONT mode during an A/C or SIMV inspiration (mandatory or spontaneous), the inspiration is completed, unaffected by the mode change. Because SPONT mode has no special breath timing require-

ments, the ventilator then enters the exhalation phase and waits for the detection of patient inspiratory effort, a manual inspiration, or apnea detection.

10.12 Apnea Ventilation

When a patient stops breathing or is no longer being ventilated, it is called apnea. When apnea is detected by the ventilator the ventilator alarms and delivers apnea ventilation according to the current apnea ventilation settings.

10.12.1 Apnea Detection

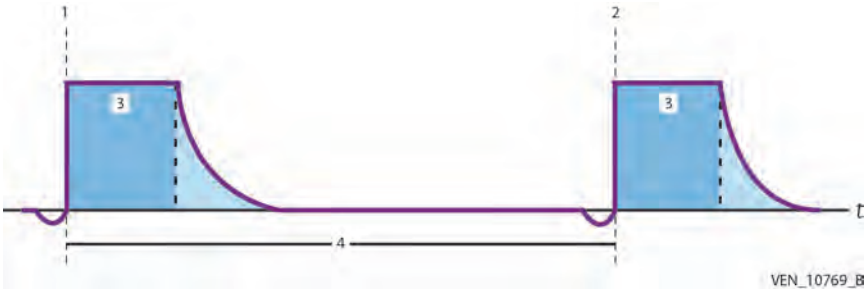
The ventilator declares apnea when no breath has been delivered by the time the operator-selected apnea interval elapses, plus a small increment of time (350 ms). This increment allows time for a patient who has begun to initiate a breath to trigger inspiration and prevent the ventilator from declaring apnea when the apnea interval is equal to the breath period.

The apnea timer resets whenever an inspiration begins, regardless of whether the inspiration is patient-triggered, ventilator-triggered, or operator-initiated. The ventilator then sets a new apnea interval beginning from the start of the current inspiration. To hold off apnea ventilation, another inspiration must be delivered before (the current apnea interval + 350 ms) elapses. Apnea detection is suspended during a disconnect, occlusion, or safety valve open (SVO) state.

Apnea is not declared when the apnea interval setting equals or exceeds the breath period. For example, if the respiratory rate setting is 4/min, an apnea interval of 15 *s* or more means apnea cannot be detected. The ventilator bases apnea detection on inspiratory (not expiratory) flow, and allows detection of a disconnect or occlusion during apnea ventilation. Apnea detection is designed to accommodate interruptions to the typical breathing pattern due to other ventilator features that temporarily extend the inspiratory or expiratory intervals (rate changes, for example) but still detect a true apnea event.

The following figure shows an apnea breath where T_A equals the breath period.

Figure 10-19. Apnea Interval Equals Breath Period



1	Tb0	3	PIM
2	Tb1	4	T_A (apnea interval)

The figure below shows an apnea breath with T_A greater than the breath period.

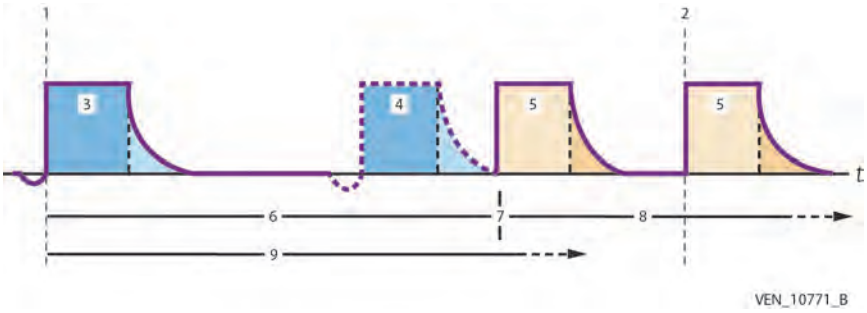
Figure 10-20. Apnea Interval Greater Than Breath Period



1	Tb0	4	VIM
2	Tb1	5	T_A (apnea interval)
3	PIM		

The following figure shows an apnea breath with T_A less than the breath period.

Figure 10-21. Apnea Interval Less Than Breath Period



1	Tb0	6	Apnea interval
2	Tb1	7	Apnea Tb0
3	PIM	8	Apnea ventilation
4	Dashed line indicates a PIM to avoid apnea	9	Tb (T_A<Tb)
5	Apnea VIM		

10.12.2 Transition to Apnea Ventilation

When apnea is declared, the ventilator delivers apnea ventilation according to the current apnea ventilation settings and displays the apnea settings on the graphical user interface (GUI). Regardless of the apnea interval setting, apnea ventilation cannot begin until inspiration of the current breath is complete and the restricted phase of exhalation has elapsed.

10.12.3 Settings Changes During Apnea Ventilation

All apnea and non-apnea settings remain active on the GUI during apnea ventilation. Both non-apnea and apnea settings changes are phased in according to the applicable rules. If apnea ventilation is active, new settings are accepted but not implemented until non-apnea ventilation begins. Allowing key entries after apnea detection allows adjustment of the apnea interval at setup, regardless of whether apnea has been detected. During apnea ventilation, the Manual Inspiration key is active, but Expiratory Pause and Inspiratory Pause keys are not active. The increase O_2 control is active during apnea ventilation, because apnea detection is likely during suctioning.

The apnea respiratory rate must be ≥ $60/T_A$. Additionally, apnea settings cannot result in an I:E ratio > 1.00:1.

10.12.4 Resetting Apnea Ventilation

Apnea ventilation is intended as an auxiliary mode of ventilation when there is insufficient breath delivery to the patient over a specified period of time. Apnea ventilation can be reset to normal ventilation by the operator (by pressing the Alarm Reset key) or the patient (autoreset). It is also reset when a rate change is made that renders apnea ventilation inapplicable.

If the patient regains inspiratory control, the ventilator returns to the operator-selected mode of non-apnea ventilation. The ventilator determines whether the patient has regained respiratory control by monitoring triggered inspirations and exhaled volume. If the patient triggers two consecutive inspirations, and the exhaled volume is equal to or greater than 50% of the delivered volume (including any compliance volume), the ventilator resets to non-apnea ventilation. Exhaled volume is monitored to avoid resetting due to autotriggering caused by large leaks in the patient circuit.

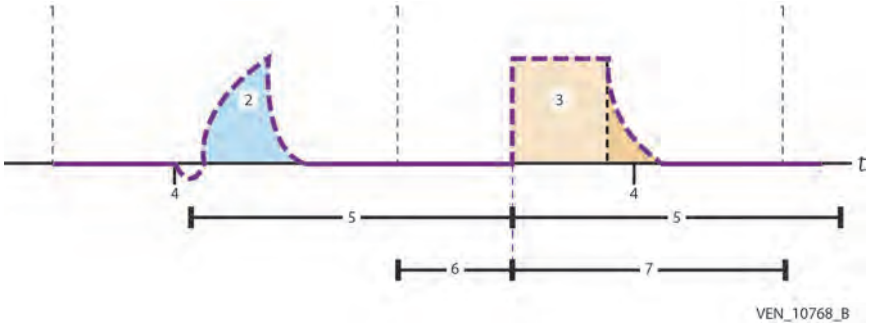
10.12.5 Apnea Ventilation in SIMV

The following strategy is designed to allow SIMV to avoid triggering apnea ventilation if a VIM breath can be delivered instead:

- If the apnea interval (T_A) elapses at any time during the mandatory interval, the ventilator delivers a VIM rather than beginning apnea ventilation.
- If T_A elapses during the spontaneous interval, apnea ventilation begins.

The following figure shows an illustration of how SIMV is designed to deliver a VIM rather than trigger apnea ventilation, when possible.

Figure 10-22. Apnea Ventilation in SIMV



1	Tb	5	T_A
2	Last breath (PIM)	6	Tm (If T_A elapses during Tm, ventilator delivers a VIM rather than beginning apnea ventilation
3	VIM	7	Ts
4	Tm max		

10.12.6 Phasing in New Apnea Intervals

How a new apnea interval is phased in depends on whether or not apnea ventilation is active. If apnea ventilation is active, the ventilator accepts and implements the new setting immediately. During normal ventilation (that is, apnea ventilation is not active), these rules apply

- If the new apnea interval setting is shorter than the current (or temporarily extended) apnea interval, the new value is implemented at the next inspiration.
- If the new apnea interval setting is longer than the current (or temporarily extended) apnea interval, the old interval is extended to match the new interval immediately.

10.13 Detecting Occlusion and Disconnect

10.13.1 Occlusion

The ventilator detects severe patient circuit occlusions in order to protect the patient from excessive airway pressures, or from receiving little or no gas. Occlusions require immediate attention to remedy.

The ventilator detects a severe occlusion if

- The inspiratory or expiratory limb of the breathing circuit is partially or completely occluded (condensate or secretions collected in a gravity-dependent loop, kinked or crimped tubing, etc.).
- The ventilator EXHAUST port is blocked or resistance through the port is too high.
- The exhalation valve fails in the closed position (occlusion detection at the From patient port begins after 195 ms of exhalation has passed.)

The ventilator does not detect a severe occlusion if:

- The pressure difference between the inspiratory and the expiratory transducers is less than or equal to 5 cmH_2O.
- The exhalation valve fails in the closed position and the pressure in the exhalation limb is less than 2 cmH_2O.
- Silicone tubing is attached to the EXHAUST port of the ventilator (i.e. for metabolic monitoring purposes).

The ventilator checks the patient circuit for occlusions during all modes of breathing (except Stand-by state and Safety Valve Open) at delivery of every breath. Once the circuit check begins, the ventilator detects a severe occlusion of the patient circuit within 200 ms. The ventilator checks the EXHAUST port for occlusions during the expiratory phase of every breath (except during disconnect and safety valve open). Once the EXHAUST port check begins, the ventilator detects a severe occlusion within 100 ms following the first 200 ms of exhalation. All occlusion checking is disabled during pressure sensor autozeroing.

When an occlusion is detected, an alarm sounds, the ventilator enters the OSC (Occlusion Status Cycling) state and displays a message indicating the length of time the patient has gone without ventilation (how long the ventilator has been in OSC). This alarm has the capability to autoreset, since occlusions such as those due to patient activity (for example, crimped, or kinked tubing) can correct themselves.

Once a severe occlusion is detected, the ventilator acts to minimize airway pressure. Because any severe occlusion places the patient at risk, the ventilator minimizes the risk while displaying the length of time the patient has been without ventilatory support. Severe occlusion is detected regardless of what mode or triggering strategy is in effect. When a severe occlusion is detected, the ventilator terminates normal ventilation, terminates any active alarm silence, annunciates an occlusion alarm, and enters the safe state (exhalation and inspiratory valve de-energized and safety valve open) for 15 *s* or until inspiratory pressure drops to 5 cmH_2O or less, whichever comes first.

During a severe occlusion, the ventilator enters OSC, in which it periodically attempts to deliver a pressure-based breath while monitoring the inspiration and expiration phases for the existence of a severe occlusion. If the severe occlusion is corrected, the ventilator detects the corrected condition after two complete OSC breath periods during which no occlusion is detected. When the ventilator delivers an OSC breath, it closes the safety valve and waits 500 ms for the safety valve to close completely, delivers a breath with a target pressure of 15 cmH_2O for 2000 ms, then cycles to exhalation. This breath is followed by a mandatory breath according to the current settings, but with PEEP = 0 and O_2% equal to 100% for adult/pediatric circuit types or 40% for neonatal circuits. During OSC (and only during OSC), the $\overline{\uparrow}P_{PEAK}$ (high circuit pressure) alarm limit is disabled to ensure it does not interfere with the ability of the ventilator to detect a corrected occlusion. When the ventilator does not detect a severe occlusion, it resets the occlusion alarm, re-establishes PEEP, and reinstates breath delivery according to current settings.

Inspiratory and expiratory pause, and manual inspirations are suspended during a severe occlusion. Pause maneuvers are canceled by a severe occlusion. During a severe occlusion, ventilator settings changes are possible. Severe occlusions are not detected when the ventilator is in the Safety Valve Open (SVO) state.

A corrected occlusion is detected within 15 *s*.

10.13.2 Disconnect

A circuit disconnect condition is detected when the ventilator cannot ensure that a patient is receiving sufficient tidal volume (due to a large leak or disconnected patient circuit). This discussion applies when Leak Sync is disabled.

When a disconnect is detected, an alarm sounds, the ventilator indicates that a disconnect has been detected, and displays a message indicating the length of time the patient has gone without ventilation.

Patient data are not displayed during a circuit disconnect condition.

The ventilator monitors the expiratory pressure and flow, delivered volume, and exhaled volume to declare a disconnect using any of these methods

- The ventilator detects a disconnect when the expiratory pressure transducer measures no circuit pressure and no exhaled flow during the first 200 ms of exhalation. The ventilator postpones declaring a disconnect for another 100 ms to allow an occlusion (if detected) to be declared first, because it is possible for an occlusion to match the disconnect detection criteria.

- Despite many possible variations of circuit disconnections and/or large leaks, it is possible for a patient to generate some exhaled flow and pressure. The ventilator then uses the disconnect sensitivity (D_{SENS}, the percentage of delivered volume lost during the exhalation phase of the same breath to declare a disconnect) setting to detect a disconnect.
- If the disconnect occurs during a spontaneous breath, a disconnect is declared when the inspiration is terminated by maximum inspiratory time (or the $\overline{\uparrow}T_{I\ SPONT}$ limit setting when Vent Type is non-invasive [NIV]) and the ventilator detects inspiratory flow rising to the maximum allowable.
- If the disconnect occurs at the endotracheal tube, the exhaled volume will be much less than the delivered volume for the previous inspiration. The ventilator declares a disconnect if the exhaled volume is lower than the D_{SENS} setting for three consecutive breaths. The D_{SENS} setting helps avoid false detections due to leaks in the circuit or the patient's lungs, and the three-consecutive-breaths requirement helps avoid false detections due to a patient out-drawing the ventilator during volume control (VC) breaths.
- Flow less than a value determined using the D_{SENS} setting and pressure less than 0.5 cmH_2O detected for ten (10) consecutive seconds during exhalation.

WARNING:
When vent type is NIV, and D_{SENS} setting is turned OFF, the system may not detect large leaks and some disconnect conditions it would declare as alarms during INVASIVE ventilation.

Once the ventilator detects a patient circuit disconnect, the ventilator declares a high-priority alarm and discontinues breath delivery, regardless of what mode (including apnea) was active when the disconnect was detected. If there is an active alarm silence when the disconnect occurs, the alarm silence is NOT cancelled. The ventilator displays the length of time the patient has been without ventilatory support. During the disconnect, the exhalation valve closes, idle flow (10 L/min flow at 100% O_2 or 40% O_2 in NeoMode, if available with Leak Sync disabled and 20 L/min with Leak Sync enabled) begins, and breath triggering is disabled. A message appears identifying how long the patient has gone without ventilatory support.

The ventilator monitors both expiratory flow and circuit pressures to detect reconnection. The ventilator declares a reconnect if any of the following criteria are met for the applicable time interval:

- Exhaled idle flow within the reconnect threshold is detected.
- Inspiratory and expiratory pressures are both above or both below reconnect threshold levels or,

- Inspiratory pressure rises to a reconnect level.

If the disconnect condition is corrected, the ventilator detects the corrected condition within one second.

Ventilator triggering, apnea detection, expiratory and inspiratory pause, manual inspirations, and programmed maneuvers or one-time events are suspended during a patient circuit disconnect condition. Spirometry is not monitored during a disconnect, and all alarms based on spirometry values are disabled. During a disconnect condition, ventilator settings changes are possible.

If the disconnect alarm is autoreset or manually reset, the ventilator re-establishes PEEP. Once PEEP is reestablished, the ventilator reinstates breath delivery according to settings in effect before the disconnect was detected.

Circuit disconnect detection is not active during OSC, SVO, or prior to patient connection.

10.13.3 Annunciating Occlusion and Disconnect Alarms

Occlusion and disconnection cannot be declared at the same time. Therefore, the ventilator annunciates only the first event to be declared.

10.14 Respiratory Mechanics

Reference *Respiratory Mechanics Maneuvers*, p. 4-28 for instructions on how to perform these maneuvers.

In addition to Inspiratory Pause and Expiratory Pause maneuvers, the ventilator can provide other respiratory maneuvers, including Negative Inspiratory Force (NIF), Occlusion Pressure ($P_{0.1}$) and Vital Capacity (VC), as well as automatic calculations of lung function and performance, such as Dynamic Compliance (C_{DYN}) and Dynamic Resistance (R_{DYN}), Peak Expiratory Flow (PEF), End Expiratory Flow (EEF), C_{20}/C, and Peak Spontaneous Flow (PSF).

Respiratory maneuvers can be performed in all breathing modes (except as noted below) but are not available during the following conditions:

- Apnea ventilation
- Safety PCV
- Occlusion Status Cycling (OSC)

- Non-invasive ventilation (NIV)
- When the circuit type is neonatal
- SVO
- Ventilator is in Stand-by state
- When any other respiratory maneuver has already taken place during the same breath

The GUI also displays any maneuver request, distinguishing between requests that are accepted or rejected, and any maneuver that has begun, ended, or has been canceled.

When a maneuver is selected, a GUI information panel is opened, displaying the maneuver name, user prompts and controls, and recent calculated results.

Any maneuver is canceled automatically upon declaration of any of the following alarms:

- $\uparrow P_{PEAK}$ alarm
- $\uparrow P_{VENT}$ alarm
- $\uparrow V_{TI}$

The following Respiratory Mechanics maneuvers are not available in BiLevel ventilation:

- – Occlusion Pressure
- NIF – Negative Inspiratory Force
- VC – Vital Capacity

10.14.1 Inspiratory Pause

Note:
Inspiratory pause and expiratory pause maneuvers can be performed directly by pressing the respective keys on the GUI or by swiping the Menu tab on the left side of the GUI. For more information on how to perform Respiratory Mechanics Maneuvers from the Menu tab, Reference *Respiratory Mechanics Maneuvers*, p. 4-28.

An inspiratory pause extends the inspiratory phase of a single mandatory breath for the purpose of measuring end inspiratory circuit pressure which is used to calculate static compliance of the patient's lungs and thorax (C_{STAT}),

static resistance of the respiratory system (R_{STAT}), and inspiratory plateau pressure (P_{PL}). To calculate these pressures, the inspiratory and exhalation valves are closed, allowing pressures on both sides of the artificial airway to equalize, revealing the actual lung inflation pressure during a no-flow condition. An inspiratory pause can be either automatically or manually administered, and is only available during the next mandatory breath in A/C, SIMV, BiLevel or SPONT modes. In BiLevel, an inspiratory pause maneuver is scheduled for the next inspiration prior to a transition from P_H to P_L. Only one inspiratory pause is allowed per breath. An inspiratory pause cannot occur during apnea ventilation, safety PCV, Stand-by state, Occlusion, and SVO.

An **automatic** inspiratory pause begins when the inspiratory pause key is pressed momentarily or the maneuver is started from the GUI screen. Reference *To access respiratory mechanics maneuvers*, p. 4-28 for more information on performing respiratory mechanics maneuvers from the Menu tab on the GUI rather than using the keys on the GUI. The pause lasts at least 0.5 second but no longer than three(3) *s*. A **manual** inspiratory pause starts by pressing and holding the inspiratory pause key. The pause lasts for the duration of the key press (up to seven(7) *s*).

An active **manual** inspiratory pause is considered complete if any of the following occur:

- The inspiratory pause key is released and at least two seconds of inspiratory pause have elapsed or pressure stability conditions have been detected for not less than 0.5 *s*.
- Pause duration reaches seven (7) *s*.

A **manual** inspiratory pause maneuver request (if the maneuver is not yet active) will be canceled if any of events1-10 occur. Reference *Inspiratory and Expiratory Pause Events*.

Table 10-5. Inspiratory and Expiratory Pause Events

Event Identifier	Event
1	There is a loss of communications with the GUI
2	High ventilator pressure limit ($\overline{\uparrow}P_{VENT}$) is reached
3	High circuit pressure limit ($\overline{\uparrow}P_{PEAK}$) is reached
4	A disconnect is detected
5	Occlusion is detected

Table 10-5. Inspiratory and Expiratory Pause Events (Continued)

Event Identifier	Event
6	Apnea is detected
7	72 seconds have elapsed without an inspiratory pause after one has been requested
8	INSPIRATION TOO LONG alarm is detected
9	High inspired tidal volume ($\uparrow V_{TI}$) alarm is detected
10	High compensation pressure ($\uparrow P_{COMP}$) alarm is detected
11	*Cancel* is touched if maneuver is initiated from the GUI screen.
12	Safety Valve Open (SVO) is detected
13	Patient trigger effort causes circuit pressure to go below sensitivity. The sensitivity level is the setting value for pressure trigger or the backup pressure value for flow trigger
14	BUV is entered
15	Expiratory pause key is pressed (Inspiratory pause key if maneuver is an expiratory pause)

During a **manual** inspiratory pause, the maneuver is terminated if any of events 1,3,5,6,12,or 13 occur. Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

An inspiratory pause maneuver is ignored if the ventilator is in Apnea ventilation, safety PCV, OSC, SVO, BUV, or Stand-by state.

An active **automatic** inspiratory pause maneuver is terminated and exhalation begun if any of events1-12, or 14 occur. Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

The active **automatic** inspiratory pause maneuver is considered complete if the pause duration reaches three seconds or pressure stability conditions have been detected for not less than 0.5 *s*.

An **automatic** inspiratory pause maneuver request (if the maneuver is not yet active) will be canceled if any of events1-9, 11, 12, 14, or 15 occur. Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

Other characteristics of inspiratory pause include:

- During an inspiratory pause, the apnea interval (T_A) is extended by the duration of the inspiratory pause.
- If the ventilator is in SIMV, the breath period during which the next scheduled VIM occurs will also be extended by the amount of time the inspiratory pause is active.
- All activations of the inspiratory pause control are logged in the Patient Data Log.
- Severe occlusion detection is suspended
- When calculating I:E ratio, inspiratory pause is considered part of the inspiration phase.
- The expiratory time remains unchanged, and will result in a change in the I:E ratio for the breath that includes the inspiratory phase.

Once the inspiratory Pause maneuver is completed the operator can review the quality of the maneuver waveform and accept or reject the maneuver data.

10.14.2 Expiratory Pause

An expiratory pause extends the exhalation phase of a single breath in order to measure end expiratory lung pressure ($PEEP_{TOT}$) and allows intrinsic PEEP ($PEEP_I$) to be calculated as $PEEP_{TOT}$ minus set PEEP. The pressures on either side of the artificial airway are allowed to equalize by closing the inspiratory and exhalation valves. Expiratory pause is available in A/C, SIMV, and BiLevel modes. For A/C and SIMV, the expiratory pause maneuver is scheduled for the next end-of-exhalation prior to a mandatory breath. In BiLevel, the expiratory pause occurs at the next end-of-exhalation prior to a transition from P_L to P_H. Only one expiratory pause per breath is allowed, and the expiratory pause request is rejected if an inspiratory pause has already taken place during the same breath.

A request for an expiratory pause maneuver is ignored in apnea ventilation, safety PCV, SPONT, OSC, BUV, and Stand-by. Reference *To access respiratory mechanics maneuvers*, p. 4-28 for more information on performing these maneuvers from the GUI screen rather than using the keys on the GUI.

Either **manual** or **automatic** expiratory pause maneuvers can occur. A momentary press of the expiratory pause key begins an automatic expiratory pause which lasts at least 0.5 *s*, but no longer than 3.0 *s*. A **manual** expiratory pause starts by pressing and holding the expiratory pause key and lasts for the duration of the key-press (up to 15 *s*).

An active **manual** expiratory pause is terminated if any of events1-12 occur. Reference Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

An active **manual** expiratory pause is complete if the expiratory pause key is released and at least three (3) *s* of expiratory pause have elapsed, pressure stability conditions have been detected for ≥ 0.5 *s*, or pause duration lasts 15 *s*.

An active **automatic** expiratory pause is terminated if any of events1,3, or 11-13 occur. Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

An active **automatic** expiratory pause is complete if pause duration reaches three (3) *s* or pressure stability conditions have been detected for ≥ 0.5 *s*, or pause duration lasts 15 *s*.

The **automatic** expiratory pause maneuver request (the maneuver is not yet active) is canceled if events1-9, 11, 12, or 15 occur. Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

The **automatic** expiratory pause maneuver is terminated and inspiration begun if any of events1,3,or 11-13 occur. Reference *Inspiratory and Expiratory Pause Events*, p. 10-51.

Other characteristics of expiratory pause include:

- During an active manual expiratory pause, severe occlusion detection is suspended.
- When calculating I:E ratio, the expiratory pause is considered part of the exhalation phase.
- During the expiratory pause, the inspiratory time remains unchanged, so the I:E ratio is changed for the breath that includes the expiratory pause.
- All activations of the expiratory pause control are logged in the Patient Data log.

Once the expiratory pause maneuver is completed the operator can review the quality of the maneuver waveform and accept or reject the maneuver data.

10.14.3 Negative Inspiratory Force (NIF) Maneuver

The Negative Inspiratory Force (NIF) maneuver is a coached maneuver where the patient is prompted to draw a maximum inspiration against an occluded airway (the inspiratory and exhalation valves are fully closed).

A NIF maneuver is canceled if:

- Disconnect is detected
- Occlusion is detected

- SVO is detected
- ↑P_{PEAK} alarm is declared
- ↑P_{VENT} alarm is declared
- ↑V_{TI} alarm is declared
- Communications with the GUI is lost
- The maneuver has been active for 30 *s* and an inspiration is not detected
- INSPIRATION TOO LONG alarm is declared
- A manual inspiration is requested

When a NIF maneuver is activated, a single pressure-time waveform grid is automatically displayed. During a NIF maneuver, the circuit pressure displays on the waveforms screen and is regularly updated, producing a real-time display.

When an active NIF maneuver ends successfully, the calculated NIF result appears on the waveforms screen and on the maneuver panel. The NIF value displayed represents the maximum negative pressure from PEEP.

When a NIF maneuver ends, a PEEP restoration breath is delivered to the patient, then normal breath delivery resumes.

10.14.4 $P_{0.1}$ Maneuver (Occlusion Pressure)

$P_{0.1}$ is the negative airway pressure (delta pressure change) generated during the first 100 ms of an occluded inspiration. It is an estimate of the neuromuscular drive to breathe.

When a $P_{0.1}$ maneuver ends successfully, the calculated airway pressure displays on the waveforms screen and on the maneuver panel. A $P_{0.1}$ maneuver is terminated if seven (7) *s* elapse and a trigger has not been detected to activate the maneuver.

A $P_{0.1}$ maneuver is canceled if

- Disconnect is detected
- Occlusion is detected
- SVO is detected

- ↑P_{PEAK} alarm is declared
- ↑P_{VENT} alarm is declared
- ↑V_{TI} alarm is declared
- INSPIRATION TOO LONG alarm is declared
- Communications with the GUI is lost
- A manual inspiration is requested

10.14.5 Vital Capacity (VC) Maneuver

The Vital Capacity (VC) maneuver is a coached maneuver where the patient is prompted to draw a maximum inspiration (regardless of the current settings) and then to slowly and fully exhale.

When the Vital Capacity maneuver becomes active, the ventilator delivers a spontaneous inspiration in response to patient effort (with P_{SUPP} = 0, Rise time % = 50, and E_{SENS} = 0), and then allows for a full exhalation effort.

When a Vital Capacity maneuver is requested, a single Volume-Time waveform grid is automatically displayed. A Vital Capacity maneuver is canceled if:

- Disconnect is detected
- Occlusion is detected
- SVO is detected
- ↑P_{PEAK} alarm is declared
- ↑P_{VENT} alarm is declared
- ↑V_{TI} alarm is declared
- INSPIRATION TOO LONG alarm is declared
- Communications with the GUI is lost
- A manual inspiration is requested
- The maneuver as been active for 15 *s* and inspiration is not detected
- The *Cancel* is touched

When an active VC maneuver ends successfully, the calculated expiratory volume displays on the waveforms screen and on the maneuver panel and a PEEP restoration breath is delivered.

10.15 Ventilator Settings

10.15.1 Apnea Ventilation

Apnea ventilation is a backup mode and starts if the patient fails to breathe within the apnea interval (T_A) set by the operator. T_A defines the maximum allowable length of time between the start of inspiration and the start of the next inspiration. Available settings include mandatory type (PC or VC). For PC breaths the allowable settings are

- Apnea interval (T_A)
- Inspiratory pressure (P_I)
- Inspiratory time (T_I)
- Respiratory rate (*f*)

For VC breaths, the allowable settings are:

- Apnea interval (T_A)
- Flow pattern
- O_2 %
- Peak inspiratory flow ($\dot{V}_{MAX}$)
- Respiratory rate (*f*)
- Tidal Volume (V_T)

During apnea ventilation with PC selected as the mandatory type, rise time % is fixed at 50%, and the constant parameter during a rate change is inspiratory time (T_I).

If apnea is possible (that is, if (60/f) > T_A) increasing the non-apnea O_2% setting automatically changes apnea ventilation O_2% if it is not already set higher than the new non-apnea O_2%. Apnea ventilation O_2% does not automatically change by decreasing the non-apnea O_2%. Whenever there is an

automatic change to an apnea setting, a message appears on the GUI, and the apnea settings screen appears.

During apnea ventilation, changes to all non-apnea ventilation settings are allowed, but the new settings do not take effect until the ventilator resumes normal ventilation. Being able to change T_A during apnea ventilation can avoid immediately re-entering apnea ventilation once normal ventilation resumes.

Because the minimum value for T_A is ten (10) *s*, apnea ventilation cannot take place when non-apnea *f* is greater than or equal to 5.8/min.The ventilator does not enter apnea ventilation if T_A is equal to the breath period interval. Set T_A to a value less than the expected or current breath period interval as a way of allowing the patient to initiate breaths while protecting the patient from the consequences of apnea.

10.15.2 Circuit Type and Predicted Body Weight (PBW)

Together, circuit type and PBW (displayed in lb or kg) provide the basis for new patient values and absolute limits on various ventilator settings such as tidal volume (V_T) and Peak flow ($\dot{V}_{MAX}$). Run SST in order to change the circuit type.The table below gives the minimum, maximum, and new patient default values for V_T based on circuit type.

Table 10-6. Values for V_T Based on Circuit Type

Circuit Type	New Patient Default	Minimum V_T	Maximum V_T
Neonatal	When mandatory type is VC+, MAX {2 mL, (mL/kg Ratio x PBW)} mL; When mandatory type is VC, MAX {3 mL, (mL/kg Ratio * PBW)} mL	2 mL if NeoMode 2.0 software option is installed	315 mL
Pediatric	mL/kg ratio x PBW mL	25 mL	1590 mL
Adult	mL/kg ratio x PBW mL	25 mL	2500 mL

Reference *Ventilator Settings Range and Resolution*, p. 11-8, V_T setting, for more information on V_T calculations based on PBW and circuit type.

Table 10-7. Peak Flow and Circuit Type (Leak Sync Disabled)

Circuit Type	Maximum peak flow ($\dot{V}_{MAX}$) setting
Neonatal	30 L/min
Pediatric	60 L/min
Adult	150 L/min

PBW determines constants for breath delivery algorithms, some user-settable alarms, the high spontaneous inspiratory time limit setting ($\overline{\uparrow}T_{I\ SPONT}$) in NIV, and the non-settable INSPIRATION TOO LONG alarm.

10.15.3 Vent Type

There are two Vent Type choices — INVASIVE and NIV (non-invasive). INVASIVE ventilation is conventional ventilation used with endotracheal or tracheostomy tubes. All installed software options, breathing modes, breath types, and trigger types are available during INVASIVE ventilation.

NIV interfaces include non-vented full-faced or nasal masks or nasal prongs. Reference *NIV Breathing Interfaces*, p. 4-22 for a list of interfaces that have been successfully tested with NIV).

NIV enables the ventilator to handle large system leaks associated with these interfaces by providing pressure-based disconnect alarms, minimizing false disconnect alarms, and replacing the INSPIRATION TOO LONG alarm with a High Spontaneous Inspiratory Time limit ($\overline{\uparrow}T_{I\ SPONT}$) setting and visual indicator.

The following list shows the subset of INVASIVE settings active during NIV:

- **Mode —** A/C, SIMV, SPONT. (BiLevel is not available during NIV.)
- **Mandatory Type —** PC or VC. (VC+ is not available during NIV.)
- **Spontaneous Type —** PS (TC and VS are not available during NIV.)

During NIV alarm setup, the clinician may set alarms to OFF and must determine if doing so is appropriate for the patient's condition.

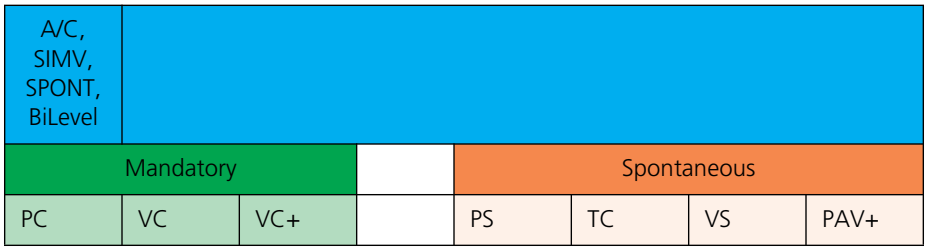
10.15.4 Mode and Breath Type

Specifying the mode defines the types and sequences of breaths allowed for both INVASIVE and NIV Vent Types.

Table 10-8. Modes and Breath Types

Mode	Mandatory Breath Type	Spontaneous Breath Type	Sequence
A/C	INVASIVE: VC, VC+, or PC NIV: VC or PC	Not allowed	All mandatory (patient-, ventilator-, or operator-initiated)
SIMV	INVASIVE: PC, VC, or VC+ NIV: VC or PC	Pressure supported (PS) or TC.	Each new breath begins with a mandatory interval, during which a patient effort yields a synchronized mandatory breath. If no patient effort is detected during the mandatory interval, the ventilator delivers a mandatory breath. Subsequent patient efforts before the end of the breath yield spontaneous breaths.
SPONT	Not allowed (PC or VC allowed only for manual inspirations).	INVASIVE: Pressure supported (PS), Tube compensated (TC), Volume supported (VS), Proportionally assisted (PAV+) NIV: PS	All spontaneous (except for manual inspirations).
BiLevel (INVASIVE vent type only)	PC	PS, TC	Combines mandatory and spontaneous breathing modes. Reference *Appendix A* for more information on BiLevel ventilation.
CPAP	VC or PC (allowed only for OIM breaths)	N/A	All spontaneous (except for manual inspirations).Reference *Appendix E*, NeoMode 2.0 for more information on CPAP.

Breath types must be defined before settings can be specified. There are only two categories of breath type: mandatory and spontaneous. Mandatory breaths are volume controlled (VC) or pressure controlled (PC or VC+). The ventilator currently offers spontaneous breaths that are pressure supported (PS) volume supported (VS), tube compensated (TC), or proportionally assisted (PAV+), if the PAV+ option is installed. The figure below shows the modes and breath types available on the ventilator.



The mode setting defines the interaction between the ventilator and the patient.

- Assist/control (A/C) mode allows the ventilator to control ventilation within boundaries specified by the practitioner. All breaths are mandatory, and can be PC, VC, or VC+.
- Spontaneous (SPONT) mode allows the patient to control ventilation. The patient must be able to breathe independently, and exert the effort to trigger ventilator support.
- Synchronous Intermittent Mandatory Ventilation (SIMV) is a mixed mode that allows a combination of mandatory and spontaneous interactions. In SIMV, the breaths can be spontaneous or mandatory, mandatory breaths are synchronized with the patient's inspiratory efforts, and breath delivery is determined by the *f* setting.
- BiLevel is a mixed mode that combines both mandatory and spontaneous breath types. Breaths are delivered in a manner similar to SIMV mode with PC selected, but providing two levels of pressure. The patient is free to initiate spontaneous breaths at either pressure level during BiLevel.

Changes to the mode are phased in at the start of inspiration. Mandatory and spontaneous breaths can be flow- or pressure-triggered, or IE Sync triggered (if the IE Sync software option is installed).

The ventilator automatically links the mandatory type setting to the mode setting. During A/C or SIMV modes, once the operator has specified volume or pressure, the ventilator displays the appropriate breath parameters. Changes in the mandatory type are phased in at the start of inspiration.

10.15.5 Respiratory Rate (*f*)

The *f* setting determines the minimum number of mandatory breaths per minute for ventilator-initiated mandatory breaths in A/C, SIMV, and BiLevel modes.If the mode is A/C or SIMV and VC is the breath type, specifying $\dot{V}_{MAX}$ and flow pattern determines T_I, T_E, and I:E. In PC breaths, specifying T_I auto-

matically determines the other timing variables. Reference *Inspiratory Time (T_I)*, p. 10-65 for an explanation of the interdependencies of *f*, T_I, T_E, and I:E. Changes to the *f* setting are phased in at the start of inspiration.

The ventilator does not accept a proposed *f* setting if it would cause the new T_I or T_E to be less than 0.2 second, the T_I to be greater than eight(8) *s*, or I:E ratio greater than 4.00:1. (The ventilator also applies these restrictions to a proposed change to the apnea respiratory rate, except that apnea I:E cannot exceed 1.00:1. An exception to this rule occurs in BiLevel ventilation where the proposed *f* setting will allow the I:E ratio to be greater than 4.00:1 only until the minimum T_L is reached.

10.15.6 Tidal Volume (V_T)

The V_T setting determines the volume of gas delivered to the patient during a VC mandatory breath. The delivered V_T is compensated for BTPS and patient circuit compliance. Changes to the V_T setting are phased in at the start of inspiration. The V_T setting only affects the delivery of mandatory breaths.

When proposing a change to the V_T setting, the ventilator compares the new value with the settings for *f*, $\dot{V}_{MAX}$, flow pattern, and T_{PL}. If the proposed setting would result in an I:E ratio that exceeds 4.00:1 or a T_I greater than eight(8) *s* or less than 0.2 *s*, or a T_E less than 0.2 *s*, the ventilator disallows the change.

10.15.7 Peak Inspiratory Flow ($\dot{V}_{MAX}$)

The $\dot{V}_{MAX}$ setting determines the maximum rate of delivery of tidal volume to the patient during mandatory VC breaths, only. Changes to $\dot{V}_{MAX}$ are phased in at the start of inspiration. Mandatory breaths are compliance compensated, even at the maximum $\dot{V}_{MAX}$ setting. Circuit compliance compensation does not cause the ventilator to exceed the ventilator's maximum flow capability.

When proposing a change to the $\dot{V}_{MAX}$ setting, the ventilator compares the new value with the settings for V_T, *f*, flow pattern, and T_{PL}. It is impossible to set a new $\dot{V}_{MAX}$ that would result in an I:E ratio that exceeds 4.00:1, or a T_I greater than 8.0 *s* or less than 0.2 *s*, or a T_E less than 0.2 *s*.

10.15.8 Plateau Time (T_{PL})

The T_{PL} setting determines the amount of time inspiration is held in the patient's airway after inspiratory flow has ceased. T_{PL} is available only during VC mandatory breaths (for A/C and SIMV mode, and operator-initiated mandatory breaths). T_{PL} is not available for PC mandatory breaths. Changes to the T_{PL} setting are phased in at the start of inspiration.

When proposing a change to the T_{PL} setting, the ventilator computes the new I:E ratio and T_I, given the current settings for V_T, f, $\dot{V}_{MAX}$, and flow pattern. It is impossible to set a new T_{PL} that would result in an I:E ratio that exceeds 4.00:1, or a T_I greater than eight(8) *s* or less than 0.2 *s*, or a T_E less than 0.2 *s*. For the I:E ratio calculation, T_{PL} is considered part of the inspiration phase.

10.15.9 Flow Pattern

The flow pattern setting defines the gas flow pattern of volume-controlled (VC) mandatory breaths only. The selected values for V_T and $\dot{V}_{MAX}$ apply to both the square or descending ramp flow patterns. If V_T and $\dot{V}_{MAX}$ and are held constant, T_I approximately halves when the flow pattern changes from descending ramp to square (and approximately doubles when flow pattern changes from square to descending ramp), and corresponding changes to the I:E ratio also occur. Changes in flow pattern are phased in at the start of inspiration.

The settings for flow pattern, V_T,*f*, T_{PL}, and $\dot{V}_{MAX}$ are interrelated. If any setting change would cause any of the following, the ventilator does not allow that change

- I:E ratio > 4:1
- T_I > 8.0 *s* or T_I < 0.2 *s*
- T_E < 0.2 s

10.15.10 Flow Sensitivity ($\dot{V}_{SENS}$)

The $\dot{V}_{SENS}$ setting defines the rate of flow inspired by a patient that triggers the ventilator to deliver a mandatory or spontaneous breath. When $\dot{V}_{-TRIG}$ is selected, a base flow of gas (1.5 L/min) travels through the patient circuit during the

ventilator's expiratory phase. Once a value for flow sensitivity is selected, the ventilator delivers a base flow equal to $\dot{V}_{SENS}$ + 1.5 L/min (base flow is not user-selectable). When the patient inhales and their inspiratory flow exceeds the $\dot{V}_{SENS}$ setting, a trigger occurs and the ventilator delivers a breath. Reductions to $\dot{V}_{SENS}$ are phased in immediately, while increases are phased in at the start of exhalation.

When $\dot{V}_{SENS}$ is active, it replaces pressure sensitivity (P_{SENS}). The $\dot{V}_{SENS}$ setting has no effect on the P_{SENS} setting. $\dot{V}_{SENS}$ can be active in any ventilation mode (including pressure supported, volume controlled, pressure controlled, and apnea ventilation). When $\dot{V}_{SENS}$ is active, a backup P_{SENS} setting of 2 cmH_2O is in effect to detect the patient's inspiratory effort, even if the flow sensors do not detect flow.

Although the minimum $\dot{V}_{SENS}$ setting of 0.2 L/min (adult/pediatric circuit types) or 0.1 L/min (neonatal circuit type) can result in autotriggering, it can be appropriate for very weak patients. The maximum setting of 20 L/min (adult/pediatric circuit types) or 10 L/min (neonatal circuit type) is intended to avoid autotriggering when there are significant leaks in the patient circuit.

10.15.11 Pressure Sensitivity (P_{SENS})

The P_{SENS} setting selects the pressure drop below baseline (PEEP) required to begin a patient-initiated breath (either mandatory or spontaneous). Changes to P_{SENS} are phased in immediately. The P_{SENS} setting has no effect on the $\dot{V}_{SENS}$ setting and is active only if the trigger type is P_{-TRIG}.

Lower P_{SENS} settings provide greater patient comfort and require less patient effort to initiate a breath. However, fluctuations in system pressure can cause autotriggering at very low settings. The maximum P_{SENS} setting avoids autotriggering under worst-case conditions if patient circuit leakage is within specified limits.

10.15.12 Inspiratory Pressure (P_I)

The P_I setting determines the pressure at which the ventilator delivers gas to the patient during a PC mandatory breath. The P_I setting only affects the delivery of PC mandatory breaths. The selected P_I is the pressure above PEEP. (For example, if PEEP is set to five cmH_2O, and P_I is 20 cmH_2O, the ventilator deliv-

ers gas to the patient at 25 cmH_2O.) Changes to the P_I setting are phased in at the start of inspiration.

The sum of PEEP + P_I + 2 cmH_2O cannot exceed the high circuit pressure ($\bar{\uparrow}P_{PEAK}$) limit. To increase this sum of pressures, first raise the $\bar{\uparrow}P_{PEAK}$ limit before increasing the settings for PEEP or P_I. The minimum value for P_I is 5 cmH_2O and the maximum value is 90 cmH_2O.

10.15.13 Inspiratory Time (T_I)

The T_I setting determines the time during which an inspiration is delivered to the patient for PC mandatory breaths. The ventilator accepts a setting as long as the resulting I:E ratio and T_E settings are valid. Changes to T_I phase in at the start of inspiration. Directly setting T_I in VC mandatory breaths is not allowed.

The ventilator rejects settings that result in an I:E ratio greater than 4.00:1, a T_I greater than eight(8) *s* or less than 0.2 *s*, or a T_E less than 0.2 *s* to ensure the patient has adequate time for exhalation.

Setting *f* and T_I automatically determines the value for I:E and T_E.

$$60/f - T_I = T_E$$

This equation summarizes the relationship between T_I, I:E,T_E, and breath period time

$$T_I = \left(\frac{60}{f}\right)((I:E)/(1 + I:E))$$

If the *f* setting remains constant, any one of the three variables (T_I, I:E, or T_E) can define the inspiratory and expiratory intervals. If the *f* setting is low (and additional spontaneous patient efforts are expected), T_I can be a more useful variable to set than I:E. As the *f* setting increases (and the fewer patient-triggered breaths are expected), the I:E setting becomes more relevant. Regardless of which variable is chosen, a breath timing bar always shows the interrelationship between T_I, I:E,T_E, and *f*.

10.15.14 Expiratory Time (T_E)

The T_E setting defines the duration of exhalation for PC and VC+ mandatory breaths, only. Changes to the T_E setting are phased in at the start of exhalation. Setting *f* and T_E automatically determines the value for I:E ratio and T_I. Reference *Inspiratory Time (T_I)*, p. 10-65 for an explanation of the interdependencies of *f*, T_I, T_E, and I:E.

10.15.15 I:E Ratio

The I:E ratio setting is available when I:E is selected as the constant during rate change. The I:E setting determines the ratio of inspiratory time to expiratory time for mandatory PC breaths. The ventilator accepts the specified range of direct I:E ratio settings as long as the resulting T_I and T_E settings are within the ranges established for mandatory breaths. Changes to the I:E ratio phase in at the start of inspiration. Directly setting the I:E ratio in VC mandatory breaths is not allowed. Reference *Inspiratory Time (T_I)*, p. 10-65 for an explanation of the interdependencies of *f*, T_I, T_E, and I:E.

Setting *f* and I:E automatically determine the values for T_I and T_E. The maximum I:E ratio setting of 4.00:1 is the maximum that allows adequate time for exhalation and is intended for inverse ratio pressure control ventilation.

10.15.16 High Pressure (P_H) in BiLevel

The pressure level entered by the operator for the inspiratory phase of the mandatory breath in BiLevel ventilation.

10.15.17 Low Pressure (P_L) in BiLevel

The pressure level entered by the operator for the expiratory phase of the mandatory breath in BiLevel ventilation.

10.15.18 High Time (T_H) in BiLevel

The duration of time (in seconds) the ventilator maintains the set high pressure level in BiLevel ventilation.

10.15.19 Low Time (T_L) in BiLevel

The duration of time (in seconds) the ventilator maintains the set low pressure level in BiLevel ventilation.

10.15.20 T_H:T_L Ratio in BiLevel

The ratio of T_H to T_L in BiLevel ventilation, similar to I:E ratio when ventilating a patient without BiLevel.

10.15.21 PEEP

This setting defines the positive end-expiratory pressure (PEEP), also called baseline airway pressure. PEEP is the positive pressure maintained in the patient circuit during exhalation. Changes to the PEEP setting are phased in at the start of exhalation.

The sum of

- PEEP + 7 cmH_2O, or
- PEEP + P_I + 2 cmH_2O (if PC is active), or
- PEEP + P_{SUPP} + cmH_2O (if PS is on)

cannot exceed the $\bar{\uparrow}P_{PEAK}$ limit. To increase the sum of pressures, first raise the $\bar{\uparrow}P_{PEAK}$ limit before increasing the settings for PEEP, P_I, or P_{SUPP}.

If there is a loss of PEEP from occlusion, disconnect, Safety Valve Open, or loss of power conditions, PEEP is re-established (when the condition is corrected) by the ventilator delivering a PEEP restoration breath. The PEEP restoration breath is a 1.5 cmH_2O pressure-supported breath with exhalation sensitivity of 25%, and rise time % of 50%. A PEEP restoration breath is also delivered at the conclusion of Vent Startup. After PEEP is restored, the ventilator resumes breath delivery at the current settings.

Note:
PEEP restoration breath parameters are not user adjustable.

10.15.22 Pressure Support (P_{SUPP})

The P_{SUPP} setting determines the level of positive pressure above PEEP applied to the patient's airway during a spontaneous breath. P_{SUPP} is only available in SIMV, SPONT, and BiLevel, in which spontaneous breaths are allowed. The P_{SUPP} setting is maintained as long as the patient inspires, and patient demand determines the flow rate. Changes to the P_{SUPP} setting are phased in at the start of inspiration. The pressure support setting affects only spontaneous breaths.

The sum of PEEP +P_{SUPP} +2 cmH_2O cannot exceed the $\overline{\uparrow}P_{PEAK}$ limit. To increase the sum of pressures, first raise the $\overline{\uparrow}P_{PEAK}$ limit before increasing the settings for PEEP or P_{SUPP}. Since the $\overline{\uparrow}P_{PEAK}$ limit is the highest pressure considered safe for the patient, a P_{SUPP} setting that would cause a $\uparrow P_{PEAK}$ alarm requires re-evaluating the maximum safe circuit pressure.

10.15.23 Volume Support ($V_{T\ SUPP}$)

Volume support ($V_{T\ SUPP}$) is defined as the volume of gas delivered to the patient during spontaneous VS breaths. Changes to the to the $V_{T\ SUPP}$ setting are phased in at the start of inspiration.

10.15.24 % Supp in TC

In TC, the% Supp setting represents the amount of the imposed resistance of the artificial airway the TC breath type will eliminate by applying added pressure at the patient circuit wye. For example, if the % Supp setting is 100%, TC eliminates 100% of the extra work imposed the by the airway. At 50%, TC eliminates 50% of the added work from the airway. TC is also used with BiLevel, and is available during both P_H and P_L phases.

10.15.25 % Supp in PAV+

In PAV+, the % Supp setting represents the percentage of the total work of breathing provided (WOB) by the ventilator. Higher inspiratory demand yields greater support from the ventilator. The patient performs the remaining work. If the total WOB changes (resulting from a change to resistance or compliance) the percent support remains constant.

10.15.26 Rise Time %

The rise time % setting allows adjustment of the speed at which the inspiratory pressure reaches 95% of the target pressure. Rise time settings apply to PS (including a setting of 0 cmH_2O),VS, PC, or VC+ breaths. The higher the value of rise time %, the more aggressive (and hence, the more rapid) the rise of inspiratory pressure to the target (which equals PEEP + P_I (or P_{SUPP})). The rise time % setting only appears when pressure-based breaths are available. The range of rise time % is 1% to 100%. A setting of 50% takes approximately half the time to reach 95% of the target pressure as a setting of 1.

- For mandatory PC, VC+, or BiLevel breaths, a rise time setting of 1 produces a pressure trajectory reaching 95% of the inspiratory target pressure (PEEP + P_I) in two (2) s or 2/3 of the T_I, whichever is shortest.
- For spontaneous breaths (VS, or PS), a rise time setting of 1 produces a pressure trajectory reaching 95% of the inspiratory target (PEEP + P_{SUPP}) in (0.4 x PBW-based T_I TOO LONG x 2/3) *s*.
- When both PC and PS breaths are active, the slopes and thus the pressure trajectories can appear to be different. Changes to T_I and P_I cause PC pressure trajectories to change. Changes in rise time % are phased in at the start of inspiration.
- When P_{SUPP} = 0, the rise time % setting determines how quickly the ventilator drives circuit pressure to PEEP + 1.5 cmH_2O.

10.15.27 Expiratory Sensitivity (E_{SENS})

The E_{SENS} setting defines the percentage of the measured peak inspiratory flow at which the ventilator cycles from inspiration to exhalation in all spontaneous breath types unless IE Sync has been selected for inspiratory and expiratory detection. When inspiratory flow falls to the level defined by E_{SENS}, exhalation begins. E_{SENS} is a primary setting and is accessible from the GUI screen. Changes to E_{SENS} are phased in at the next patient-initiated spontaneous inspiration.

E_{SENS} complements rise time %. Rise time % should be adjusted first to match the patient's inspiratory drive, and then the E_{SENS} setting should cause ventilator exhalation to occur at a point most appropriate for the patient. The higher the E_{SENS} setting, the shorter the inspiratory time. Generally, the most appropriate E_{SENS} is compatible with the patient's condition, neither extending nor shortening the patient's intrinsic inspiratory phase.

E_{SENS} in a PAV+ breath is expressed in L/min instead of percent.

10.15.28 Disconnect Sensitivity (D_{SENS})

Disconnect sensitivity (D_{SENS}) is defined as the percentage of returned volume lost due to a leak, above which the ventilator declares a CIRCUIT DISCONNECT alarm (when Leak Sync is not enabled). When D_{SENS} is set to its lowest value (20%) it has the highest sensitivity for detecting a leak or disconnect. Conversely, when D_{SENS} is set to its highest value (95%), the ventilator is least sensitive to a leak or disconnect, because greater than 95% of the returned volume must be lost before the alarm annunciates. During NIV, the D_{SENS} value is automatically set to OFF, which is means that returned volume loss is not considered and the alarm will not sound.D_{SENS} with Leak Sync enabled is expressed in L/min instead of percent.

Note:
If D_{SENS} is set to OFF during NIV, the ventilator is still capable of declaring a CIRCUIT DISCONNECT alarm.

Note:
D_{SENS} cannot be turned OFF if Leak Sync is enabled.

Changes to D_{SENS} are phased in at the start of inspiration.

10.15.29 High Spontaneous Inspiratory Time Limit ($\overline{\uparrow}T_{I\ SPONT}$)

The high spontaneous inspiratory time limit setting ($\overline{\uparrow}T_{I\ SPONT}$) is available only in SIMV or SPONT modes during NIV, and provides a means for setting a maximum inspiratory time after which the ventilator automatically transitions to exhalation. The default $\overline{\uparrow}T_{I\ SPONT}$ setting is based upon circuit type and PBW.

For pediatric/adult circuit types, the new patient default value is (1.99 + (0.02 x PBW)) s

For neonatal circuit types, the new patient default value is ((1.00 + (0.10 x PBW) s

The $\uparrow T_{I\ SPONT}$ indicator appears on the primary display at the beginning of a ventilator-initiated exhalation and remains visible for as long as the ventilator

truncates breaths in response to the $\overline{\uparrow}T_{I\ SPONT}$ setting. The $\uparrow T_{I\ SPONT}$ indicator disappears when the patient's inspiratory time returns to less than the $\overline{\uparrow}T_{I\ SPONT}$ setting, or after 15 seconds has elapsed after the beginning of exhalation of the last truncated breath. Changes to $\overline{\uparrow}T_{I\ SPONT}$ are phased in at the start of inspiration.

10.15.30 Humidification Type

The humidification type setting sets the type of humidification system (heated expiratory tube, non-heated expiratory tube, or heat-moisture exchanger -- HME) used on the ventilator and can be changed during normal ventilation or short self test (SST). Changes in humidification type phase in at the start of inspiration.

SST calibrates spirometry partly based on the humidification type. Changing the humidification type without rerunning SST can affect the accuracy of spirometry and delivery.

The accuracy of the exhalation valve flow sensor varies depending on the water vapor content of the expiratory gas, which depends on the type of humidification system in use. Because the temperature and humidity of gas entering the expiratory filter differ based on the humidification type being used, spirometry calculations also differ according to humidification type. For optimum accuracy, rerun SST to change the humidification type.

10.15.31 Humidifier Volume

The dry, compressible volume in mL of the humidification chamber for the humidification type entered during SST. Only applies if a humidifier is used.

10.16 Safety Net

While the ventilator is designed to be as safe and as reliable as possible, Covidien recognizes the potential for problems to arise during mechanical ventilation, either due to user error, patient-ventilator interactions, or because of problems with the ventilator itself. Safety Net is a broad term that includes strategies for handling problems that arise in the "patient-ventilator" system (patient problems) as well as strategies to minimize the impact of system faults on patient safety. In these scenarios, The ventilator is designed to alarm and to

provide the highest level of ventilation support possible. in case of ventilator malfunction. If the ventilator is not capable of ventilatory support, it opens the patient circuit and allows the patient to breathe from room air if able to do so (this emergency state is called ***Safety Valve Open (SVO)***. Safety mechanisms are designed to be verified periodically or to have redundancy. The ventilator is designed to ensure that a single-point failure does not cause a safety hazard or affect its ability to annunciate a high-priority audible alarm.

10.16.1 User Error

The ventilator is designed to prevent the operator from implementing settings that are clearly inappropriate for the patient's predicted body weight (PBW). Each setting has either soft bounds (can be overridden) or hard bounds (no override allowed) that alert the operator to the fact that the settings may be inappropriate for the patient. In the event that the patient is connected without any parameters being specified, the ventilator enters Safety PCV, a safe mode of ventilation regardless of the circuit type in use (neonatal, pediatric, or adult) or patient's PBW. Safety PCV is entered after POST, if a patient connection is made prior to settings confirmation. Safety PCV uses New Patient default settings with exceptions shown in the following table:

Table 10-9. Safety PCV Settings

Parameter	Safety PCV value
PBW	Neonatal: 3 kg Pediatric:15 kg Adult: 50 kg
mode	A/C
mandatory type	PC
f_{TOT} (total respiratory rate)	Neonatal: 25 1/min Pediatric: 16 1/min Adult: 16 1/min
T_I	Neonatal: 0.3 s Pediatric: 0.7 s Adult: 1 s
P_I	15 cmH_2O
O_2%	Neonatal: 40% Pediatric: 100% Adult: 100%

Table 10-9. Safety PCV Settings (Continued)

Parameter	Safety PCV value
PEEP	3 cmH_2O
Trigger type	Neonatal: $\dot{V}_{-TRIG}$ Pediatric: P_{-TRIG} Adult: P_{-TRIG}
P_{SENS}	2 cmH_2O
$\dot{V}_{SENS}$	1.0 L/min
$\uparrow P_{PEAK}$	20 cmH_2O
$\uparrow \dot{V}_{E\ TOT}$ alarm	OFF
$\downarrow \dot{V}_{E\ TOT}$ alarm	0.05 L/min
$\uparrow V_{TE}$ alarm	OFF
$\downarrow V_{TE\ MAND}$ alarm	OFF
$\downarrow V_{TE\ SPONT}$ alarm	OFF
Circuit type	Last set value, or adult if none available
Humidification type	Set value, or 'NON-HEATED EXP TUBE' if none available
Humidifier volume	Last set value, or 480 mL if none available

Note:
In Safety PCV, expiratory pauses are not allowed.

10.16.2 Patient Related Problems

In case of patient problems, the ventilator remains fully operative and annunciates the appropriate alarm. The detection, response, and priority of each patient-related alarm is determined by the actual patient problem. Reference *Alarms*, p. 6-4 for a comprehensive description of the patient alarm system.

10.16.3 System Related Problems

The ventilator is designed to prevent system faults. Its modular design allows the breath delivery unit (BDU) to operate independently of the graphical user

interface (GUI) and several modules of the breath delivery sub-system have redundancy that, if certain faults occur, provides for ventilatory support using settings that do not depend on the suspect hardware. System faults include the following:

- Hardware faults (those that originate inside the ventilator and affect its performance)
- Soft faults (faults momentarily introduced into the ventilator that interfere with normal operation
- Inadequate supply (AC power or external gas pressure)
- Patient circuit integrity (occluded or disconnected circuit)

10.16.4 Background Diagnostic System

The ventilator has an extensive system of continuous testing processes. If an error is detected in the background diagnostic system, the ventilator notifies the operator by posting an entry in the diagnostic log. If the ventilator experiences an anomaly which causes an unintended reset, the ventilator will recover from that reset and deliver a breath within three(3) s without any operator intervention. After recovering from a reset, the ventilator uses the same settings that were in effect before the reset occurred.

The background test process compares monitored values of ventilator functions with expected values of ventilator sensors under normal conditions regardless of whether the ventilator is in Stand-by or is ventilating a patient. The ventilator will continue to ventilate the patient with the highest level of support possible, and may revert to one of the states described. Reference *Ventilator Protection Strategies*, p. 4-35.

Background tests include

- Periodically initiated tests performed at intervals of a specific number of machine cycles. These tests check hardware components directly affecting breath delivery, safety mechanisms, and the GUI, and detect and correct corruption of control variable data.
- Boundary checks performed at every analog measurement. These checks verify measurement circuitry, including sensors.

Ventilation Assurance is a safety net feature invoked if the Background Diagnostics detect a problem with certain components in either the gas mix subsystem, the inspiratory subsystem, or the expiratory subsystem. Each subsystem has a Backup Ventilation strategy that allows ventilation to continue by bypassing the suspect components giving the operator time to replace the ventilator.

Mix BUV is invoked if the measured gas mix is significantly different from the set mix, if the accumulator pressure is out of range or if a fault is indicated in the mix PSOLs or flow sensors. During MIX BUV, the normal mix controller is bypassed and ventilation continues as set, except that the gas mix reverts to 100% Oxygen or Air, depending on where the fault indication was detected. Backup circuits then control the pressure in the accumulator to keep it in the proper range for the Inspiratory Module.

Inspiratory BUV is invoked if Background Diagnostics detect a problem in the inspiratory module (PSOL and/or flow sensor signal out of range). In inspiratory BUV, ventilation continues with the following settings:

Table 10-10. Inspiratory Backup Ventilation Settings

Backup Ventilation parameter	Setting
PBW	Previously used setting during Vent Startup
Mode	A/C
Mandatory type	PC
f	Neonatal: 25 1/min Pediatric: 16 1/min Adult: 16 1/min
T_I	Neonatal: 0.3 s Pediatric: 0.7 s Adult: 1 s
P_I	15 cmH_2O above PEEP
O_2%	100% (21% if O_2 not available)
PEEP	3 cmH_2O
T_{PL}	0 s
Trigger type	$\dot{V}_{-TRIG}$; 2 L/min (adult/pediatric), 1.5 L/min (neonatal)
Gas flow	Controlled by pressure in the mix accumulator

During inspiratory BUV, the delivery PSOL is disabled, but gas delivery is achieved via an inspiratory BUV solenoid valve, the gas flow being created by pressure in the mix accumulator.

Exhalation BUV is invoked if problems with the Exhalation Valve driver are detected. A backup analog circuit is enabled to control the exhalation valve

though the more advanced control features (active exhalation valve control) are not functional.

Note:
During Mix and Inspiratory BUV, gas supply to installed options is disabled.

Entry into BUV is logged in the alarm log and system diagnostic log, and the status display provides an indicator that the ventilator is in BUV and which subsystem is affected.

When in BUV, a high priority alarm is annunciated, and the GUI displays an alarm banner indicating BUV, blanks patient data, and a displays a pressure waveform.

If the ventilator cannot provide any degree of reliable ventilatory support and fault monitoring, then the ventilator alarms and enters the safety valve open (SVO) emergency state. During SVO, the ventilator de-energizes the safety, expiratory, and inspiratory valves, annunciates a high-priority alarm, and turns on the SVO indicator. During SVO, a patient can spontaneously inspire room air (if able to do so) and exhale. Check valves on the inspiratory and expiratory sides minimize rebreathing of exhaled gas during SVO. During SVO the ventilator

- Displays the elapsed time without ventilatory support
- Does not display patient data (including waveforms)
- Does not detect patient circuit occlusion or disconnect conditions

Visible indicators on the ventilator's GUI and status display illuminate when the ventilator is in the SVO state. Other safeguards built into the ventilator include a one-way valve (check valve) in the inspiratory pneumatic circuit allowing the patient to inhale through the safety valve with limited resistance. This check valve also limits exhaled flow from entering the inspiratory limb to reduce the possibility of re-breathing exhaled CO_2 gas.

10.17 Power On Self Test (POST)

Every time the ventilator is powered on or resets and at the beginning of Short Self Test (SST) and Extended Self Test (EST) it performs Power On Self Test (POST). POST checks the integrity of the GUI and Breath Delivery subsystems and communication channels without operator intervention and takes approximately twelve(12) *s* to complete.

If POST detects a major fault, qualified service personnel must correct the problem and successfully pass EST. Reference the *Puritan Bennett™ 980 Series Ventilator Service Manual* for more details on POST.

10.18 Short Self Test (SST)

- SST is a short (about 5 minutes) and simple sequence of tests that verifies proper operation of breath delivery hardware (including pressure and flow sensors), checks the patient circuit (including tubing, humidification device, and filters) for leaks, and measures the circuit compliance and resistance. SST also checks the resistance of the expiratory filter. SST, in normal mode, can only be performed at start up, prior to initiation of ventilation. Covidien recommends running SST every 15 days, between patients, and when changing the patient circuit or its configuration (including changing circuit type, adding or removing in-line water traps, or using a different type or style of patient circuit). Reference *To run SST*, p. 3-48. The ventilator does not allow access to SST if it senses a patient is connected.

10.19 Extended Self Test (EST)

EST verifies the integrity of the ventilator's subsystems using operator participation. EST requires a "gold standard" test circuit and a stopper to block the patient wye. All test resources, including the software code to run EST, exist in the ventilator. EST testing, excluding tests of optional equipment (such as the extended battery) takes about ten (10) minutes. Reference *EST (Extended Self Test)*, p. 3-52.

WARNING:
Do not enter Service mode with a patient attached to the ventilator. Serious injury could result.

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11 Specifications

11.1 Overview

This chapter contains the following specifications for the Puritan Bennett™ 980 Series Ventilator:

- Physical
- Electrical
- Interface
- Environmental
- Performance (Ranges, resolution, and accuracies for ventilator settings, alarm settings, and patient data)
- Regulatory Compliance

WARNING:
Due to excessive restriction of the Air Liquide™, SIS, and Dräger™ hose assemblies, reduced ventilator performance levels may result when oxygen or air supply pressures < 50 psi (345 kPa) are employed.

11.2 Measurement Uncertainty

Table 11-1. Performance Verification Equipment Uncertainty

Measured Parameter	Offset	Gain
Flow	0.1001 SLPM	2.7642 % reading
Pressure	0.121594 cmH_2O	0.195756 % reading
Oxygen Concentration	0.0168 % O_2	0.0973 % reading
Temperature	0.886041 °C	0.128726 % reading
Atmospheric Pressure	1.76 cmH_2O	-

During breath delivery performance verification for flow and pressure based measurements, the equipment inaccuracy is subtracted from the acceptance specification as follows:

- Net Acceptance Gain = Requirement Specification Gain - Measurement Uncertainty Gain
- Net Acceptance Offset = Requirement Specification Offset - Measurement Uncertainty Offset
- Acceptance Limit = ± [(Net Acceptance Offset) + (Net Acceptance Gain) x (Setting)]
- (Setting- Acceptance Limit) ≤ Measurement ≤ (Setting + Acceptance Limit)

For derived parameters, such as volume, compliance, etc., the individual sensor uncertainties are combined and applied as applicable to determine the acceptance limits.

11.3 Physical Characteristics

Table 11-2. Physical Characteristics

Weight	113 lb (51.26 kg) including BDU, GUI, standard base, and primary battery BDU only: 69 lb (31.3 kg)
Dimensions	Ventilator: 12.5" width x 11.5" depth x 43.5" height (32 cm x 30 cm x 111 cm) (not including GUI screen) Ventilator: 12.5" width x 11.5" depth x 58" height (32 cm x30 cm x 148 cm) (including GUI screen Standard base: 22.5" width x 26" depth (58 cm x 66 cm)
A-weighted sound pressure level, ventilator (average)	At a distance of one (1) meter, does not exceed 48 dBA at 5 L/min
A-weighted sound power level, ventilator	Does not exceed 58 dBA below 500 mL/min
Connectors	Inspiratory and expiratory limb connectors are 22 mm OD conical fittings compliant with ISO 5356-1
Inspiratory/ Expiratory filters	Reference filter Instructions For Use for complete specifications
Pressure units (chosen by operator)	Hectopascal (hPa) centimeters of water (cmH_2O)
Displayed weight units	Kilograms (kg) or Pounds (lb) (user selectable)
Displayed length units	Centimeters (cm) or Inches (in) (user selectable)

Table 11-3. Pneumatic Specifications

Oxygen and air inlet supplies	Pressure: 241 to 600 kPa (35 psi to 87 psi) Flow: Maximum of 200 L/min
Oxygen sensor life	Up to one year. Operating life varies depending on oxygen usage and ambient temperature.
Gas mixing system	Range of flow from the mixing system: Up to 150 L/min for Adult patients. Additional flow is available (peak flow to 200 L/min) for compliance compensation Up to 80 L/min for pediatric circuit type Up to 30 L/min for neonatal circuit type Leakage from one gas system to another: Meets IEC 80601-2-12 standard Operating pressure range: 35 psi to 87 psi (241 to 600 kPa)

Table 11-4. Technical Specifications

Maximum limited pressure (P_{LIMmax})	A fixed pressure limit to the safety valve limits circuit pressure to < 125 cmH_2O (123 hPa) at the patient wye.
Maximum working pressure (P_{Wmax})	P_{Wmax} is ensured by the high pressure limit ($\bar{\uparrow}P_{PEAK}$) when P_I is 125 cmH_2O (98.07 hPA)
Response time to change in FiO_2 setting from 21% to 90% O_2 (measured at the patient wye)	< 18 s for volumes > 150 mL < 19 s for volumes ≥ 30 mL but ≤ 150 mL < 20 s for volumes ≥ 2 mL but < 30 mL
Measuring devices	Pressure measurements: Type: Solid stated differential pressure transducer Sensing position: Inspiratory module; expiratory module Mean circuit pressure (P_{MEAN}): -20 cmH_2O (-20 hPa) to 130 cmH_2O (127 hPa) Peak circuit pressure (P_{PEAK}): -20 cmH_2O (-20 hPa) to 130 cmH_2O (127 hPa) Volume Measurements: Type: Hot film anemometer Sensing position: Inspiratory module; expiratory module Oxygen measurement: Type: Galvanic cell Sensing position: Inspiratory module
Minute volume ($\dot{V}_{E\ TOT}$) capability, ventilator	Up to 75 L/min
Results of ventilator testing using circuits identified for use with the ventilator system	

Table 11-4. Technical Specifications (Continued)

Internal Inspiratory filter bacterial/viral filtration efficiency	> 99.999%
Internal Inspiratory filter particle filtration efficiency	> 99.97% retention of particles 0.3 μm nominal at 100 L/min flow
Internal Inspiratory filter resistance	0.2 cmH_2O < resistance < 2.2 cmH_2O at 30 L/min flow 0.2 cmH_2O < resistance < 1.7 cmH_2O at 15 L/min flow
External Inspiratory filter resistance	0.2 cmH_2O < resistance < 2.2 cmH_2O at 30 L/min flow 0.2 cmH_2O < resistance < 2.2 cmH_2O at 15 L/min flow
Combined inspiratory filter resistance	0.2 cmH_2O < resistance < 5.5 cmH_2O at 30 L/min flow 0.2 cmH_2O < resistance < 1.7 cmH_2O at 15 L/min flow
External Inspiratory filter resistance	0.2 cmH_2O < resistance < 2.2 cmH_2O at 30 L/min flow 0.2 cmH_2O < resistance < 1.7 cmH_2O at 15 L/ min flow
External Inspiratory filter bacterial/viral filtration efficiency, reusable	> 99.999%
External Inspiratory filter particle filtration efficiency, reusable	> 99.97% retention of particles 0.3 μm nominal at 100 L/min flow
External Inspiratory filter resistance, reusable	0.2 cmH_2O < resistance < 4.2 cmH_2O at 60 L/min 0.2 cmH_2O < resistance < 2.2 cmH_2O at 30 L/min 0.2 cmH_2O < resistance < 1.7 cmH_2O at 15 L/min
External Inspiratory filter bacterial/viral filtration efficiency, disposable	> 99.999%
External Inspiratory filter particle filtration efficiency, disposable inspiratory filter	> 99.97% retention of particles 0.3 μm nominal at 100 L/min flow
Expiratory filter particle filtration efficiency, reusable	> 99.97% retention of particles 0.3 μm nominal at 100 L/min flow
Expiratory filter bacterial/viral filtration efficiency, reusable	> 99.999%
Expiratory filter resistance (pediatric/adult, reusable and disposable)	< 2.5 cmH_2O at 30 L/min when new < 1.7 cmH_2O at 15 L/min

Table 11-4. Technical Specifications (Continued)

Expiratory filter bacterial/viral filtration efficiency, disposable	> 99.999%
Expiratory filter particle filtration efficiency, disposable	> 99.97% retention of particles 0.3 μm nominal at 100 L/min flow
Expiratory filter bacterial/viral filtration efficiency neonatal, disposable)	> 99.999%
Expiratory filter particle filtration efficiency (neonatal, disposable)	> 99.97% retention of particles 0.3 μm nominal at 100 L/min flow
Expiratory filter resistance (neonatal, disposable)	< 0.58 cmH_2O at 2.5 L/min
Circuit compliance	NEONATAL: < 0.25 mL/cmH_2O to > 3.0 mL/cmH_2O PEDIATRIC: 1.05 mL/cmH_2O to 9 mL/cmH_2O ADULT: 1.05 mL/cmH_2O to 12 mL/cmH_2O
Inspiratory limb circuit resistance	NEONATAL: 0.2 cmH_2O/L/s to 3.5 cmH_2O/L/s PEDIATRIC: 0.2cmH_2O to 7.5 cmH_2O/L/s ADULT: 0.2cmH_2O to 12.5 cmH_2O/L/s
Expiratory limb circuit resistance	NEONATAL: 0.2 cmH_2O/L/s to 3.5 cmH_2O/L/s PEDIATRIC: 0.2cmH_2O to 7.5 cmH_2O ADULT: 0.2cmH_2O to 12.5 cmH_2O
Alarm volume (primary) Measurement uncertainty: ± 3 dBA	High priority alarm volume range (dBA): 58 (volume setting 1) to 86 (volume setting 10) Medium priority alarm volume range (dBA): 52 (volume setting 1) to 78 (volume setting 10) Low priority alarm volume range (dBA): 50 (volume setting 1) to 76 (volume setting 10) Measured 1 m from front, rear, and sides of ventilator Reference *Alarm Volume Key*, p. 6-8 for alarm volume behavior during an alarm condition.
Alarm volume (secondary) Measurement uncertainty: ± 3 dBA	Minimum 64 dBA measured 1 m from front, rear, and sides of ventilator.

11.4 Electrical Specifications

Table 11-5. Electrical Specifications

Electrical ratings	100V ~, 50-60 Hz, 2.25A 120 V ~, 50-60 Hz 1.5A 220-240 V ~, 50-60 Hz, 0.75A
Mains overcurrent release	CB1: 4 A
Earth leakage current	300 μA
Touch current	100 μA
Patient Leakage current	100 μA maximum

11.5 Interface Requirements

Table 11-6. Interface Pin Designations

Pin	Signal	Name
1	N/C	Not connected
2	RxD	Receive data
3	TxD	Transmit data
4	N/C	Not connected
5	GND	Ground
6	N/C	Not connected
7	RTS	Request to send
8	CTS	Clear to send
9	N/C	Mot connected

The pin-out for the nurse call interface is as follows:

Table 11-7. Nurse Call Pin Designations

Pin	Configuration
1	Normally closed (NC)
2	Relay common
3	Normally open (NO)
4	Not connected

11.6 Environmental Specifications

Table 11-8. Environmental Specifications

Specification	Operation	Storage
Temperature	10°C to 40°C (50°F to 104°F) Ventilator 10°C to 35°C (50°F to 95°F) Internal Battery Charger	-20°C to 70°C (-68°F to 158°F)
Atmospheric Pressure	70kPa to 106 kPa (10.15 psi to (15.37 psi)	50 kPa to 106 kPa (7.25 psi to 15.37 psi)
Altitude	-411.5 m to 3048 m (-1350 ft to 10000 ft)	6096 m max (20000 ft max)
Relative Humidity	10% to 95% non-condensing	10 to 95% non-condensing

Note:
The limits marked on the device label represent out-of-box storage conditions as follows:

- Temperature: (10°C to 40°C (50°F to 104°F)
- Pressure: 70kPa to 106 kPa (10.15 psi to 15.37 psi)
- Relative Humidity: 10% to 95% non-condensing

11.7 Performance Specifications

11.7.1 Ranges and Resolutions

Reference the table below for ranges, resolutions, accuracies, new patient default values, and dependencies, where applicable, for ventilator settings. Reference *Alarm Settings Range and Resolution*, p. 11-17 for alarm settings, and Reference *Patient Data Range and Resolution*, p. 11-19 for displayed patient data parameters.

Table 11-9. Ventilator Settings Range and Resolution

Setting	Description	Range and Resolution
Apnea ventilation	A safety mode of ventilation that starts if the patient does not receive a breath for an elapsed time exceeding the apnea interval.	See individual apnea settings.
Apnea expiratory time (T_E)	For mandatory PC apnea breaths, the time interval between the end of inspiration and the beginning of the next inspiration.	**Range:**0.20 s to 59.8 s **Resolution:** 0.01 s
Apnea I:E ratio	In PC breath types, specifies the ratio of apnea inspiratory time to apenea expiratory time.	**Range:** I:E ≤ 1.00:1 **Resolution:** 0.01 for values > 1:10.0; 0.1 for values ≤ 1:10 and > 1:100; 1 for values ≤ 1:100
Apnea flow pattern	The flow shape of the delivered mandatory volume-based (VC) apnea breath.	**Range:** SQUARE, descending ramp
Apnea inspiratory pressure (P_I)	The pressure above PEEP at which gas is delivered to the patient during mandatory PC apnea breaths.	**Range:** 5 cmH_2O to 90-PEEP cmH_2O **Resolution:** 1 cmH_2O
Apnea inspiratory time (T_I)	Same as inspiratory time for non-apnea ventilation	**Range:** 0.20 s to 8 s **Resolution:** 0.01 s in PC or VC+, 0.02 s in VC

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Apnea interval (T_A)	The time after which the ventilator transitions to apnea ventilation $T_A \geq 60/f_A$	**Range:** 10 s to 60 s or OFF in CPAP **Resolution:** 1 s
Apnea O_2 %	Determines the oxygen concentration in a standard mixture of air and oxygen	**Range:** 21%O_2 to 100% O_2 **Resolution:** 1%
Apnea peak inspiratory flow ($\dot{V}_{MAX}$)	The maximum rate of tidal volume delivery during mandatory volume-based apnea breaths.	**Range:** When mandatory type is VC: **NEONATAL:** 1 L/min to 30 L/min **PEDIATRIC:** 3.0 L/min to 60 L/min **ADULT:** 3.0 L/min to 150 L/min **Resolution:** 0.1 L/min for flows < 20 L/min (BTPS); 1 L/min for flows ≥ 20 L/min (BTPS)
Apnea respiratory rate (f_A)	Sets the number of volume- or pressure-based breaths per minute for ventilator initiated mandatory (VIM) apnea breaths	**Range:** 2.0 1/min to 40 1/min **Resolution:** 0.1 1/min for 2.0 to 9.9; 1 1/min for 10 1/min to 40 1/min
Apnea tidal volume (V_T)	Sets the volume of gas delivered to the patient's lungs during a mandatory, volume-controlled apnea breath. Apnea tidal volume is compensated for body temperature and pressure, saturated (BTPS) and the compliance of the patient circuit.	**Range:** **NEONATAL:** 3 mL to 315 mL **PEDIATRIC/ADULT:** ≥ 25 mL to 2500 mL **Resolution:** 0.1 mL < 5 mL; 1 mL for 5 mL to 100 mL; 5 mL for100 mL to 395 mL; 10 mL for values ≥ 400 mL
Apnea constant during rate change	Specifies which of the three operator-adjustable breath timing variables remains constant when respiratory rate is changed during apnea ventilation.	**Range:** T_I
Apnea mandatory type	The type of mandatory breath delivered during apnea ventilation	**Range:** PC, VC
Circuit type	Specifies the circuit for which compliance and resistance values during SST have been calculated	**Range:** NEONATAL, PEDIATRIC, ADULT

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Constant during rate change	Specifies which of the three operator-adjustable breath timing variables remains constant when respiratory rate is changed.	**Range:** I:E ratio, T_I, T_E for PC or VC+ breaths; T_H:T_L ratio, T_H,T_L in BiLevel
Disconnect sensitivity (D_{SENS})	The percentage of returned volume lost, above which the ventilator declares a circuit disconnect alarm when Leak Sync is not enabled or installed.	**Range:** (if Leak Sync not enabled) 20% to 95% or OFF **Range:** (if Leak Sync enabled) **NEONATAL:** 1 L/min to 15 L/min **PEDIATRIC:** 1 L/min to 40 L/min **ADULT:** 1L/min to 65 L/min **Resolution:** (Leak Sync not enabled) 1% **Resolution:** (Leak Sync enabled) 0.5 L/min for values< 10 L/min; 1 L/min for values ≥ 10 L/min
Expiratory sensitivity (E_{SENS})	The percentage of $\dot{V}_{MAX}$ that, when reached, causes the ventilator to cycle from inspiration to exhalation during spontaneous, pressure-based breaths	**Range:** 1% to 80% 1 L/min to 10 L/min when Spontaneous Type is PAV+. **NOTE:** Default value is not expected to need adjustment. Only adjust after becoming experienced with PAV+ and only if it is suspected that the ventilator is not cycling at the patient's end-of-inspiration.
Expiratory time (T_E)	For PC or VC+ breaths, the time interval between the end of inspiration and the beginning of the next inspiration. The end of the exhalation phase is considered to be when the flow rate at the patient wye remains less than 0.5 L/min above the base flow.	**Range:** 0.20 s **Resolution:** 0.01 s
Flow pattern	The flow shape of the delivered mandatory or VC breath	**Range:** SQUARE, descending ramp

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Flow sensitivity ($\dot{V}_{SENS}$)	For flow triggered breaths, determines the volume of flow (below the base flow) required to begin a mandatory or spontaneous patient initiated breath.	**Range:** **NEONATAL:** 0.1 L/min to 10 L/min **PEDIATRIC/ADULT:** 0.2 L/min to 20.0 L/min **Resolution:** 0.1 L/min
Gender	The patient's gender	**Range:** Male or Female
Height	The patient's height	**Range:** 19.5 cm to 280 cm; 7.5 in to 110 in **Resolution:** 0.5 cm for heights < 35 cm; 1 cm for heights < 254 cm; 2 cm for heights ≥ 254 cm; 0.25 in for heights < 14 in; 0.5 in for heights <100 in; 1 in for heights ≥ 100 in Reference *Predicted Body Weight (PBW) Calculation*, p. 4-21.
High spontaneous inspiratory time limit ($\overline{\uparrow}T_{I\ SPONT}$)	Active in NIV only, allows the operator to select the maximum spontaneous inspiratory time.	**Range:** **NEONATAL:** 0.2 s to 1.7 s **PEDIATRIC/ADULT:** 0.4 s to 5 s
Humidification type	The type of humidification system used on the ventilator	**Range:** HME, non-heated expiratory tube, heated expiratory tube
Humidifier volume	The empty fluid volume of the currently installed humidifier.	**Range:** 100 mL to 1000 mL **Resolution:** 10 mL
Elevate O_2%	The percentage of O_2 to be added to the current air/O_2 mixture for two minutes	**Range:** 1% to 100% **Resolution:** 1% between 1% and 10; 5% between 5% and 75%; jumps to 100% when increased above 75%
I:E ratio	In PC and VC+ breath types, specifies the ratio of inspiratory time to expiratory time.	**Range:** 1:299 to 149:1 **Resolution:** 0.01 for values > 1:10; 0.1 for values ≤ 1:10.0 and > 1:100.0; 1 for values ≤ 1:100 Displayed as XX:1 when I:E ≥ 1; displayed as 1:XX when I:E < 1
Inspiratory pressure (P_I)	The pressure above PEEP at which gas is delivered to the patient during mandatory PC breaths.	**Range:** 5 cmH_2O to 90 cmH_2O **Resolution:**1 cmH_2O

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Inspiratory time (T_I)	The time during which an inspiration is delivered to the patient during mandatory PC or VC+ breaths.	**Range:** 0.2 s to 8 s for mandatory PC, and VC+ breaths, (T_{PL}+ 0.2 s to 8 s in VC) **Resolution:** 0.01 s for PC or VC+ breaths; 0.02 s for VC breaths
Leak Sync (leak compensation)	Compensates for leaks during INVASIVE or non-invasive (NIV) ventilation.	**Range:** Enabled or Disabled
Mandatory type	The type of mandatory breath delivered in A/C, SPONT or SIMV modes. SPONT mode allows mandatory type selection for operator initiated mandatory (OIM) breaths.	**Range:** PC, VC, VC+
mL/kg ratio	The default tidal volume/ PBW ratio (only adjustable in Service Mode)	**Range:** 5.0 mL/kg to 10 mL/kg **Resolution:** 0.5 mL/kg

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Mode	The ventilation mode. The mode determines the allowable breath types: A/C – assist/control – a mandatory mode allowing volume controlled (VC), pressure controlled (PC), or VC+ breath types. SPONT – allows the patient to initiate the breath. Applicable SPONT breath types are pressure support (PS), volume support (VS), tube compensated (TC) or PAV+ if the PAV+ option is installed. SIMV – Synchronized Intermittent Mandatory Ventilation – a mixed ventilatory mode providing mandatory breaths and allowing a patient spontaneous breaths during the breath cycle. BiLevel – a mixed ventilatory mode combining the attributes of both mandatory and spontaneous breaths incorporating two pressure levels, P_H and P_L	**Range:** A/C, SPONT, SIMV, BiLevel (if option installed but not available when vent type is NIV; CPAP (only available when circuit type is NEONATAL and vent type is NIV))
O_2% (delivered)	Percentage of delivered oxygen in the gas mixture	**Range:** 21% to 100% **Resolution:** 1%
Peak inspiratory flow ($\dot{V}_{MAX}$)	The maximum rate of tidal volume delivery during mandatory volume-based breaths.	**Range:** When mandatory type is VC: **NEONATAL:** 1 L/min to 30 L/min **PEDIATRIC:** 3.0 L/min to 60 L/min **ADULT:** 3.0 L/min to 150 L/min **Resolution:** 0.1 L/min for values < 20 L/min (BTPS); 1 L/min for values ≥ 20 L/min (BTPS)
PEEP	Sets the positive end-expiratory pressure, defined as the pressure targeted in the patient circuit during exhalation.	Range: 0 cmH_2O to 45 cmH_2O Resolution: 0.5 cmH_2O from 0.0 to 19.5 cmH_2O; 1 cmH_2O from 20 to 45 cmH_2O

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
P_H	The positive pressure during the insufflation phase in BiLevel ventilation.	**Range:** 5 cmH_2O to 90 cmH_2O **Resolution:** 1 cmH_2O
P_L	The positive pressure in the patient circuit during the expiratory phase of BiLevel ventilation.	Range: 0 cmH_2O to 45 cmH_2O Resolution: 0.5 cmH_2O from 0.0 to 19.5 cmH_2O; 1 cmH_2O from 20 to 45 cmH_2O
Plateau time (T_{PL})	The amount of time inspiration is held in the patient's lungs after inspiratory flow ceases for volume-based mandatory breaths. Considered part of inspiratory phase for I:E ratio calculations.	**Range:** 0s to 2 s **Resolution:** 0.1 s
Predicted Body Weight (PBW)	Indicates an approximation of the patient's "ideal" body weight based upon their gender and height (or length for neonatal patients). PBW determines default limits and limits for breath delivery parameters.	**Range:** **NEONATAL:** 0.3kg (0.66 lb) to 7.0 kg (15 lb) when NeoMode 2.0 option is installed; **PEDIATRIC:** 3.5 kg (7.7 lb) to 35 kg (77 lb) **ADULT:** ≥ 25 kg (55.12 lb) **Resolution:** 0.01 kg for weights < 1 kg, 0.1 kg for weights ≥ 1 kg and < 10 kg, 1 kg for weights ≥ 10 kg
Pressure sensitivity (P_{SENS})	For pressure triggered breaths, determines the amount of pressure below PEEP required to begin a mandatory or spontaneous patient initiated breath.	**Range:** 0.1 cmH_2O to 20.0 cmH_2O **Resolution:** 0.1 cmH_2O
Pressure support (P_{SUPP}) or PS	The positive pressure above PEEP (or P_L in BiLevel) during a spontaneous breath.	**Range:** 0 cmH_2O to 70cmH_2O **Resolution:** 1 cmH_2O
Respiratory rate (*f*)	Sets the number of volume- or pressure-based breaths per minute for ventilator initiated mandatory (VIM) breaths in A/C, SIMV, and BiLevel modes	**Range:** **NEONATAL:** 1.0 1/min to 150 1/min **PEDIATRIC/ADULT:** **Resolution:** 0.1 from 1.0 1/min to 9.9 1/min; 1 1/min from 10 1/min to 150 1/min

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Rise time %	Sets the speed at which inspiratory gas delivered to the patient reaches the pressure target in BiLevel, PC, VC+, VS, or PS. Higher percentages of rise time produce inspiratory pressure trajectories with shorter time to the target value.	**Range:** 1% to 100% **Resolution:** 1%
Spontaneous type	The breath type for patient initiated spontaneous breaths in SIMV, SPONT, and BiLevel modes.	**Range:** PS, TC, PAV+, or VS
% Supp	In Tube Compensation, specifies the additional positive pressure desired to overcome resistance of the artificial airway.	**Range:**10% to 100% **Resolution:** 5%
% Supp	In PAV+, specifies the percentage of total inspiratory work of breathing (WOB) performed by the ventilator.	**Range:** 5% to 95% **Resolution:** 5%
T_H (time high)	The duration of the insufflation phase during BiLevel ventilation.	**Range:** 0.2 s to 30 s **Resolution:** 0.01 s
T_L (time low)	The duration of the expiratory phase during BiLevel ventilation.	**Range:** ≥ 0.20 s **Resolution:** 0.01 s
T_H:T_L ratio	In BiLevel, specifies the ratio of insufflation time to expiratory time	**Range:** 1:299 to 4:1; in BiLevel T_H:T_L **Resolution:** 0.01 for < 10.00:1 and > 1:10.00; 0.1for [< 100.0:1 and ≥ 10.0:1] or[≤ 1:10.0 and > 1:100.0]; 1 for < 1:100.0 or ≥ 100:1

Table 11-9. Ventilator Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Tidal volume (V_T)	The volume of gas delivered to the patient during a mandatory volume-based breath. V_T compensates for body temperature and pressure, saturated (BTPS) and circuit compliance. Applicable for volume-based breaths.	**Range:** **NEONATAL:** 2 mL to 315 mL **PEDIATRIC:** 25 mL to 1590 mL **ADULT:** 25 mL to 2500 mL **Resolution:** 0.1 mL < 5 mL; 1 mL for ≥ 5 mL and < 100 mL; 5 mL for 100 mL to 395 mL; 10 mL for values ≥ 400 mL
Volume support ($V_{T\ SUPP}$) or VS	The volume of gas delivered to the patient during spontaneous, volume supported breaths	**Range:** **NEONATAL:** 2 mL to 310 mL **PEDIATRIC:** 25 mL to 1590 mL **ADULT:** 25 mL to 2500 mL **Resolution:** 0.1 mL for ≤ 5 mL; 1 mL for 5 mL to < 100 mL; 5 mL for 100 mL to < 400 mL; 10 mL ≥ 400 mL
Trigger type	Determines whether flow changes ($\dot{V}_{-TRIG)}$, pressure changes (P_{-TRIG}), or intrapleural pressure changes (IE Sync) trigger patient breaths	**Range:** **NEONATAL:** $\dot{V}_{-TRIG}$ **PEDIATRIC/ADULT:** $\dot{V}_{-TRIG}$, P_{-TRIG} or IE Sync in SPONT (if IE Sync option installed)
Tube ID	The internal diameter of the artificial airway used to ventilate the patient.	**Range:** 4.5 mm to 10 mm when spontaneous type is TC **Range:** 6 mm to 10 mm when spontaneous type is PAV+ **Resolution:** 0.5 mm
Tube type	The type of artificial airway used to ventilate the patient.	**Range:** Endotracheal (ET), tracheal (Trach)
Ventilation type	Invasive or non-invasive (NIV) ventilation type based upon the type of breathing interface used. Invasive: ET or Trach tubes NIV: masks, infant nasal prongs, or uncuffed ET tubes	**Range:** INVASIVE, NIV

Table 11-10. Alarm Settings Range and Resolution

Setting	Description	Range and Resolution
Alarm volume	Controls the volume of alarm annunciations	**Range:** 1 (minimum) to 10 (maximum) **Resolution:** 1
Apnea Interval (T_A)	The Apnea alarm condition indicates that neither the ventilator nor the patient has triggered a breath for the operator-selected Apnea Interval (T_A). When the Apnea alarm condition is true, the ventilator invokes mandatory ventilation as specified by the operator.	**Range:** 10 s to 60 s or OFF in CPAP **Resolution:** 1 s
High circuit pressure setting ($\uparrow P_{PEAK}$)	The $\uparrow P_{PEAK}$ alarm indicates the patient's airway pressure ≥ the set alarm level	**Range:** 7 cmH_2O to 100 cmH_2O **Resolution:** 1 cmH_2O
Low circuit pressure setting ($\downarrow P_{PEAK}$)	The $\downarrow P_{PEAK}$ alarm indicates the measured airway pressure ≤ the set alarm limit during an NIV or VC+ inspiration.	**Range:** **NIV:** OFF or ≥ 0.5 cmH_2O to <100 cmH_2O **Resolution:** 0.5 cmH_2O for values < 20.0 cmH_2O; 1 cmH_2O for values ≥ 20 cmH_2O
High exhaled minute volume alarm setting ($\uparrow \dot{V}_{E\ TOT}$)	The $\uparrow \dot{V}_{E\ TOT}$ alarm indicates the measured total minute volume ≥ the set alarm limit.	**Range:** OFF and **NEONATAL:** 0.1 L/min to 10 L/ min **PEDIATRIC:** 0.1 L/min to 30 L/min **ADULT:** 0.1 L/min to 100 L/min **Resolution:** 0.005 L/min for values < 0.50 L/min; 0.05 L/min for values ≥ 0.5 L/min to < 5.0 L/min; 0.5 L/min for values ≥ 5.0 L/min

Table 11-10. Alarm Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
High exhaled tidal volume alarm setting ($\uparrow V_{TE}$)	The $\uparrow V_{TE}$ alarm indicates that the measured exhaled tidal volume ≥ the set alarm limit for spontaneous and mandatory breaths.	**Range:** OFF and **NEONATAL:** 5 mL to 500 mL **PEDIATRIC:** 25 mL to 1500 mL **ADULT:** 25 mL to 3000 mL **Resolution:** 1 mL for values < 100 mL; 5 mL for values ≥ 100 mL and < 400 mL; 10 mL for values ≥ 400 mL
High inspired tidal volume alarm limit ($\uparrow V_{TI}$)	The $\uparrow V_{TI}$ alarm indicates the delivered volume of any breath ≥ the set alarm limit.	**Range:** 6 mL to 6000 mL **Resolution:** 1 mL for values < 100 mL; 5 mL for values ≥ 100 mL to < 400 mL; 10 mL for values ≥ 400 mL
High respiratory rate alarm setting ($\uparrow f_{TOT}$)	The $\uparrow f_{TOT}$ alarm indicates the measured breath rate ≥ the set alarm limit.	**Range:** OFF or **NEONATAL:** 10 1/min to 170 1/min **PEDIATRIC/ADULT:** 10 1/min to 110 1/min **Resolution:** 1 1/min
High spontaneous inspiratory time limit ($\uparrow T_{I\ SPONT}$)	The $\uparrow T_{I\ SPONT}$ indicator allows the operator to select the maximum spontaneous inspiratory time of an NIV breath. No alarm is annunciated; only the symbol $\uparrow T_{I\ SPONT}$ appears on the screen near the NIV indicator when inspiration time exceeds the setting. If $\uparrow T_{I\ SPONT}$ is exceeded, the ventilator transitions from inspiration to exhalation.	**Range:** **NEONATAL:** 0.2 s to ≤ the value of the NIV inspiratory time limit trigger for the patient's PBW and circuit type s **PEDIATRIC/ADULT:** 0.4 s to ≤ the value of the NIV inspiratory time limit trigger for the patient's PBW and circuit type s **Resolution:** 0.1 s
Low exhaled mandatory tidal volume alarm setting ($\downarrow V_{TE\ MAND}$)	The $\downarrow V_{TE\ MAND}$ alarm indicates the measured mandatory tidal volume ≤ the set alarm limit.	**Range:** OFF and **NEONATAL:** 1 mL to 300 mL **PEDIATRIC:** 1 mL to 1000 mL **ADULT:** 1 mL to 2500 mL **Resolution:** 1.0 mL for values < 100 mL; 5 mL for values ≥ 100 mL and < 400 mL; 10 mL for values ≥ 400 mL

Table 11-10. Alarm Settings Range and Resolution (Continued)

Setting	Description	Range and Resolution
Low exhaled minute volume alarm setting ($\downarrow\dot{V}_{E\ TOT}$)	The $\downarrow\dot{V}_{E\ TOT}$ alarm indicates the measured exhaled minute volume ≤ the set alarm limit for mandatory and spontaneous breaths.	**Range:** OFF when vent type = NIV and **NEONATAL:** 0.01 L/min to 10 L/min **PEDIATRIC:** 0.05 L/min to 30 L/min **ADULT:** 0.05 L/min to 60 L/min **Resolution:** 0.005 L/min for values < 0.50 L/min; 0.05 L/min for values ≥ 0.50 L/min and < 5.0 L/min; 0.5 L/min for values > 5.0 L/min
Low exhaled spontaneous tidal volume alarm setting ($\downarrow V_{TE\ SPONT}$)	The $\downarrow V_{TE\ SPONT}$ alarm indicates the measured spontaneous tidal volume ≤ the set alarm limit.	**Range:** OFF and **NEONATAL:** 1 mL to 300 mL **PEDIATRIC:** 1 to 1000 mL ADULT: 1 to 2500 mL **Resolution:** 1 mL for values < 100 mL; 5 mL from 100 mL to < 400 mL; 10 mL for values ≥ 400 mL

Table 11-11. Patient Data Range and Resolution

Data Value	Description	Range and Resolution
Breath phase	The breath phase indicator displays the breath delivery phase (inspiration or exhalation) currently being delivered to the patient.	**Range:** Control (C), Assist (A), Spontaneous (S)
Inspired tidal volume (V_{TL}) during Leak Sync	The volume inspired for each breath when Leak Sync is enabled.	**Range:** 0 mL to 6000 mL **Resolution:** 0.1 mL for values < 10 mL; 1 mL for values 10 mL to 6000 mL
Inspired tidal volume (V_{TI})	The volume inspired for a pressure- based breath	**Range:** 0 mL to 6000 mL **Resolution:** 0.01 mL for 0 mL to 9.9 mL, 1 mL for values 10 mL to 6000 mL
Inspired tidal volume (V_{TL})during Leak Sync	The volume inspired for each breath when Leak Sync is enabled.	Range: 0 mL to 6000 mL Resolution: 1 mL for values < 10 mL; 1 mL for values 10 mL to 6000 mL

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
Dynamic compliance (C_{DYN})	The result of dividing the delivered tidal volume by the peak airway pressure.	**Range:** 0 mL/cmH_2O to 200 mL/ cmH_2O **Resolution:** 0.1 mL/cmH_2O for values < 10 mL/cmH_2O; 1 mL/ cmH_2O for values ≥ 10 mL/ cmH_2O
Dynamic resistance (R_{DYN})	The change in pressure per unit change in flow.	**Range:** 0.0 cmH_2O/L/s to 100 cmH_2O/L/s Resolution: 0.1 cmH_2O/L/ for values < 10 cmH_2O/L/s; 1 cmH_2O/ L/s for values ≥ 10 cmH_2O/L/s
End expiratory flow (EEF)	The rate of expiratory flow occurring at the end of exhalation.	**Range:** 0 to 150 L/min **Resolution:** 0.1 L/min for values < 20 L/min; 1 L/min for values ≥ 20 L/min
End expiratory pressure (PEEP)	The pressure at the end of the expiratory phase of the previous breath (also applies in BiLevel).	**Range:** -20.0 cmH_2O to 130 cmH_2O **Resolution:** 0.5 cmH_2O between -10.0 and +10.0 cmH_2O; 1 cmH_2O for values ≤ -10 cmH_2O and ≥ 10 cmH_2O
End inspiratory pressure ($P_{I\ END}$)	The pressure at the end of the inspiratory phase of the current breath (also applies in BiLevel).	**Range:** -20.0 cmH_2O to 130 cmH_2O **Resolution:** 0.1 cmH_2O for -20.0 cmH_2O to 9.9 cmH_2O; 1.0 cmH_2O for values 10 cmH_2O to 130 cmH_2O
Exhaled mandatory tidal volume ($V_{TE\ MAND}$)	The exhaled volume of the last mandatory breath. When the mode is SPONT, and no mandatory breaths have occurred for a time period ≥ 2 minutes, the $V_{TE\ MAND}$ indicator is hidden. Mandatory breaths can occur during SPONT mode via manual inspiration.	**Range:** 0 mL to 6000 mL **Resolution:** 0.1 mL for 0 mL to 9.9 mL; 1 mL for 10 mL to 6000 mL

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
Exhaled minute volume ($\dot{V}_{E\ TOT}$)	A calculated sum of the volumes exhaled by the patient for mandatory and spontaneous breaths for the previous one-minute interval (also applies in BiLevel).	**Range:** 0.00 L/min to 99.9 L/min **Resolution:** 0.01 L/min for 0.00 to 9.99 L/min; 0.1 L/min for 10.0 to 99.9 L/min
Exhaled spontaneous minute volume ($\dot{V}_{E\ SPONT}$)	The sum of exhaled spontaneous volumes per minute (also applies in BiLevel)	**Range:** 0 L/min to 99.9 L/min **Resolution:** 0.01 L/min for 0.00 to 9.99 L/min; 0.1 L/min for 10.0 to 99.9 L/min
Exhaled spontaneous tidal volume ($V_{TE\ SPONT}$)	The exhaled volume of the last spontaneous breath.	**Range:** 0 mL to 6000 mL **Resolution:** 0.1mL for 0 mL to 9.9 mL; 1 mL for 10 mL to 6000 mL
Exhaled tidal volume (V_{TE})	The volume exhaled by the patient for the previous mandatory or spontaneous breath (also applies in BiLevel.	**Range:** 0 mL to 6000 mL **Resolution:** 0.1mL for 0 mL to 9.9 mL; 1 mL for 10 mL to 6000 mL
Leak Sync exhaled tidal volume (V_{TE})	The volume exhaled by the patient for the previous mandatory or spontaneous breath during Leak Sync (also applies in BiLevel).	**Range:** 0 mL to 6000 mL **Resolution:** 0.1mL for 0 mL to 9.9 mL; 1 mL for 10 mL to 6000 mL
I:E ratio	The ratio of the inspiratory time to expiratory time for the previous breath.	**Range:** 1:599 to 149:1 **Resolution:** 0.1 for 9.9:1 to 1:9.9; 1 for 149:1 to 10:1 and 1:10 to 1:599
Inspiratory compliance (C_{20}/C)	The ratio of compliance of the last 20% of inspiration to the compliance of the entire inspiration	**Range:** 0 to 1.00 **Resolution:** 0.01
Intrinsic PEEP ($PEEP_I$)	A calculated estimate of the pressure above PEEP at the end of exhalation.	Range: -20.0 cmH_2O to +130 cmH_2O Resolution: 0.1 cmH_2O between -9.9 and +9.9 cmH_2O; 1 $cmH_2O \leq$ -10 cmH_2O and $\geq$ 10 cmH_2O

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
Mean circuit pressure (P_{MEAN})	The calculated average circuit pressure for an entire breath cycle including both inspiratory and expiratory phases (whether the breath is mandatory or spontaneous).	**Range:** -20.0 cmH_2O to 100 cmH_2O **Resolution:** 0.1 cmH_2O for -20.0 to 9.9 cmH_2O; 1 cmH_2O for 10 to 100 cmH_2O
Negative inspiratory force (NIF)	The negative pressure generated during a maximally forced inspiratory effort against an obstruction to flow.	**Range:** ≤ 0 cmH_2O to ≥ -50 cmH_2O **Resolution:** 1 cmH_2O for values ≤ -10 cmH_2O; 0.1 cmH_2O for values > -10 cmH_2O
O_2% (monitored)	The monitored percentage of oxygen in the gas delivered to the patient, measured at the ventilator outlet upstream of the inspiratory filter.	**Range:** 0% to 103% **Resolution:** 1%
$P_{0.1}$	The inspiratory depression of airway pressure after 100 ms of occlusion. $P_{0.1}$ is an indicator of respiratory drive.	Range: ≥ -20 cmH_2O to 0 cmH_2O Resolution: 1 cmH_2O when < -10 cmH_2O; 0.1 cmH_2O when ≥ -10 cmH_2O
PAV based intrinsic PEEP ($PEEP_{I\ PAV}$)	The estimated intrinsic PEEP during a PAV+ breath. Intrinsic PEEP is an estimate of the pressure above PEEP at the end of every pause exhalation.	**Range:** 0 to 130 cmH_2O **Resolution:** 0.1 cmH_2O for values < 10 cmH_2O; 1cmH_2O for values ≥ 10 cmH_2O
PAV-based lung compliance (C_{PAV})[1]	The calculated change in pulmonary volume for an applied change in patient airway pressure when measured under conditions of zero flow during a PAV+ plateau maneuver. When PAV+ is selected, the ventilator displays the current filtered value for patient compliance, and updates the display at the successful completion of each estimation. C_{PAV} can be displayed in the vital patient data banner. Reference *Vital Patient Data*, p. 3-42.	**Range:** 2.5 mL/cmH_2O to 200 mL/ cmH_2O **Resolution:** 0.1 mL/cmH_2O for values < 10 mL/cmH_2O; 1 cmH_2O for values ≥ 10 mL/ cmH_2O

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
PAV-based lung elastance (E_{PAV})[1]	For a PAV+ breath, E_{PAV} is calculated as the inverse of C_{PAV} (see above). E_{PAV} can be displayed in the vital patient data banner. Reference *Vital Patient Data*, p. 3-42.	**Range:** 5.0 cmH_2O/L to 400 cmH_2O/L **Resolution:** 0.1 cmH_2O/L for values < 10 cmH_2O/L; 1 $cmH_2O/L \geq 10$ cmH_2O/L
PAV-based patient resistance (R_{PAV})[1]	The difference between estimated total resistance R_{TOT} and the simultaneously estimated resistance of the artificial airway. When PAV+ is selected, the ventilator displays the current filtered value for patient resistance, and updates the display at the successful completion of each estimation. R_{PAV} can be displayed in the vital patient data banner. Reference *Vital Patient Data*, p. 3-42.	**Range:** 0.0 $cmH_2O/L/s$ to 60 $cmH_2O/L/s$ **Resolution:** 0.1 $cmH_2O/L/s$ for values < 10 cmH2O/L/s; 1cmH_2O/ L/s for values ≥ 10 $cmH_2O/L/s$
PAV-based total airway resistance (R_{TOT})[1]	R_{TOT} is an estimated value captured just past peak expiratory flow and is equal to the pressure loss across the patient airway plus respiratory system (patient airway + ET tube + expiratory limb of the VBS)/ expiratory flow. This pressure loss is divided by the expiratory flow estimated at the same moment, yielding the estimate for R_{TOT}.The complete operation is orchestrated and monitored by a software algorithm. When PAV+ is selected, the ventilator displays the current filtered value for total resistance, and updates the display at the successful completion of each calculation. R_{TOT} can be displayed in the vital patient data banner. Reference *Vital Patient Data*, p. 3-42.	Range: 1.0 $cmH_2O/L/s$ to 80 $cmH_2O/L/s$ Resolution: 0.1 $cmH_2O/L/s$ for values < 10 $cmH_2O/L/s$; 1 cmH_2O/ L/s for values ≥ 10 $cmH_2O/L/s$

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
PAV-based work of breathing (WOB_{TOT})	The estimated effort needed for patient inspiration including both patient and ventilator.	**Range:** 1.0 J/L to10.0 J/L **Resolution:** 0.1 J/L
Peak expiratory flow (PEF)	The maximum speed of exhalation.	**Range:** 0 to 150 L/min **Resolution:** 0.1 L/min for PEF < 20 L/min; 1 L/min for PEF ≥ 20 L/ min
Peak circuit pressure (P_{PEAK})	The maximum pressure during the previous breath, relative to the patient wye, including inspiratory and expiratory phases.	**Range:** -20.0 cmH_2O to 130 cmH_2O **Resolution:** 0.1 cmH_2O for values -20.0 cmH_2O to 9.9 cmH_2O; 1.0 cmH_2O for values 10 cmH_2O to 130 cmH_2O
Peak spontaneous flow (PSF)	The maximum flow rate sampled during a spontaneous inspiration.	**Range:** 0 to 200 L/min **Resolution:** 0.1 L/min for values < 20 L/min; 1L/min for values ≥ 20 L/min
Plateau pressure (P_{PL})	The pressure measured during an inspiratory pause maneuver.	**Range:** -20.0 cmH_2O to 130 cmH_2O **Resolution:** 0.1 cmH_2O for values -20.0 to 9.9 cmH_2O; 1.0 cmH_2O for values ≥ 10 cmH_2O
Proximal exhaled tidal volume (V_{TEY})	For neonatal patients, the exhaled volume of the previous breath measured by the Proximal Flow Sensor) (if installed).	**Range:** 0 mL to 500 mL **Resolution:** 0.1mL for values 0 mL to 9.9 mL; 1 mL for values 10 mL to 500 mL
Proximal exhaled total minute volume ($\dot{V}_{E\ TOTY}$)	For neonatal patients, the exhaled minute volume measured by the Proximal Flow Sensor)	**Range:** 0.00 to 99.9 L/min **Resolution:** 0.01 L/min for 0.00 to 9.99 L/min; 0.1 L/min for 10.0 to 99.9 L/min
Proximal inspired tidal volume (V_{TIY})	For neonatal patients, the inspired volume of the previous breath measured by the Proximal Flow Sensor) (if installed).	**Range:** 0 mL to 500 mL **Resolution:** 1 mL
Spontaneous inspiratory time ($T_{I\ SPONT}$)	The duration of the inspiratory phase of a spontaneous breath.	**Range:** 0 s to 10 s **Resolution:** 0.01 s

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
Spontaneous inspiratory time ratio (T_I/T_{TOT})	The fraction of the total spontaneous breath time used by inspiration.	**Range:** 0 to 1 **Resolution:** 0.01
Spontaneous rapid shallow breathing index (f/V_T)	A calculated value using exhaled spontaneous tidal volume. High values indicate the patient is breathing rapidly, but with little volume/breath. Low values indicate the inverse scenario.	**Range:** 0.1 1/min-L to 600 1/min- L **Resolution:** 0.1 1/min-L for values < 10 1/min-L; 1 1/min-L; for values ≥ 10 1/min-L
Static compliance (C_{STAT})	An estimate of the patient's lung-thorax static compliance or elasticity.	**Range:** 0 mL/cmH_2O to 500 mL/ cmH_2O **Resolution:** 0.1 mL/cmH_2O for values < 10 mL/; 1 mL/cmH_2O for values ≥ 10 mL/cmH_2O
Resistance (R_{STAT})	An estimate of the restrictiveness of the patient's lungs and the artificial airway.	Range: 0 cmH_2O/L/s to 500 cmH_2O /L/s Resolution: 0.1 cmH_2O/L/s for values < 10 cmH_2O/L/s, 1 cmH_2O/ L/s for values ≥ 10 cmH_2O/L/s
Total PEEP ($PEEP_{TOT}$)	The estimated pressure at the circuit wye during an expiratory pause maneuver.	**Range:** -20.0 cmH_2O to +130 cmH_2O **Resolution:** 0.1 cmH_2O for values < 10 cmH_2O; 1 cmH_2O for values ≤ -10 cmH_2O and ≥ 10 cmH_2O
Total respiratory rate (f_{TOT})	The number of mandatory or spontaneous breaths/min delivered to the patient.	**Range:** 1 to 200 1/min **Resolution:** 0.1 1/min for values < 10 1/min; 1 1/min for 10 1/min to 200 1/min
Vital capacity (VC)	The maximum amount of air that can be exhaled after a maximum inhalation.	**Range:** 0 mL to 6000 mL **Resolution:** 0.1 mL for values < 10 mL; 1 mL for values ≥ 10 mL
V_{LEAK}	Inspiratory leak volume, the total volume delivered during inspiration to compensate for the leak.	**Range:** 0 to 9000 mL **Resolution:** 1 mL

Table 11-11. Patient Data Range and Resolution (Continued)

Data Value	Description	Range and Resolution
%LEAK	Percent leak, the percentage of total delivered volume during inspiration attributed to the leak calculated as leak volume during inspiration / total delivered inspiratory volume) x 100.	**Range:** 0 to 100% **Resolution:** 1%
LEAK	Exhalation leak. The leak rate at PEEP during exhalation.	**Range:** 0L/min to 200 L/min **Resolution:** 0.1 L/min
$LEAK_Y$	Exhalation Leak at PEEP during Leak Sync, measured by the proximal flow sensor.	**Range:** 0 L/min to 200 L/min **Resolution:** 0.1 L/min

1. If the estimated value of C_{PAV}, EP_{AV}, R_{PAV}, or R_{TOT} violates expected (PBW-based) limits, parentheses around the value indicate the value is questionable. If the estimated value exceeds its absolute limit, the limit value flashes in parentheses.

Table 11-12. Delivery Accuracy

Parameter	Accuracy	Range
Inspiratory pressure (P_I)	± (3.0 + 2.5% of setting) cmH_2O	5 cmH_2O to 90 cmH_2O
End expiratory pressure (PEEP)	± (2.0 + 4% of setting) cmH_2O	0 cmH_2O to 45 cmH_2O
Pressure support (P_{SUPP})	± (3.0 + 2.5% of setting) cmH_2O	0 cmH_2O to 70 cmH_2O
Tidal volume (V_T)	For adult and pediatric circuit type settings: For T_I < 600ms: ± (10 + 10% of setting x 600 ms/ T_I ms) mL For $T_I \geq$ 600 ms ± (10 + 10% of setting) mL For neonatal circuit type settings: For setting of 2 mL (VC+ only): ± (1 + 10% of setting) mL For setting of 3 mL to 4 mL: ± (2+ 10% of setting) mL (delivered volume shall be ≥ 1 mL For setting of 5 mL to 20 mL: ±(3 + 15% of setting) For setting of ≥ 20 mL: ± (4 +10% of setting) mL	For adult and pediatric circuit type settings: 25 mL to 2500 mL For neonatal circuit type settings: 2 mL to 310 mL
O_2% (delivered)	± 3%	21% to 100%
P_H	± (2.0 + 4% of setting) cmH_2O	5 cmH_2O to 90 cmH_2O

Table 11-12. Delivery Accuracy (Continued)

Parameter	Accuracy	Range
P_L	± (2.0 + 4% of setting) cmH_2O	0 cmH_2O to 45cmH_2O

Table 11-13. Monitoring (Patient Data) Accuracy

Parameter	Accuracy	Range
Peak circuit pressure (P_{PEAK})	± (2 + 4% of reading) cmH_2O	5 cmH_2O to 90 cmH_2O
Mean circuit pressure (P_{MEAN})	± (2 + 4% of reading) cmH_2O	3 cmH_2O to 70 cmH_2O
End expiratory pressure (PEEP)	± (2 + 4% of reading) cmH_2O	0 cmH_2O to 45cmH_2O
End inspiratory pressure ($P_{I\ END}$)	± (2 + 4% of reading) cmH_2O	5 cmH_2O to 90 cmH_2O
Inspired tidal volume (V_{TI})	± (4 mL + 15% of actual) mL	2 mL to 2500 mL
Exhaled tidal volume (V_{TE})	± (4 mL + 10% of actual) mL	2 mL to 2500 mL
Inspired tidal volume during Leak Sync (V_{TL})	For adult and pediatric circuit type settings: For $T_I \leq$ 600ms: ± (10 + 20% x 600 ms/T_I ms of reading) mL For $T_I >$ 600 ms: ± (10 + 20% of reading) mL For neonatal circuit type setting: ± (10 + 20% of reading) mL For readings < 100 mL, the accuracy shall apply when the percentage of inspiratory leak volume is less than 80%	For adult and pediatric circuit type settings: 25 mL to 2500 mL For neonatal circuit type settings: 2 mL to 310 mL
Exhaled tidal volume (V_{TE}) during Leak Sync	For adult and pediatric circuit type settings: For $T_E \leq$ 600ms: ± (10 + 20% x 600 ms/T_E ms of reading) mL For $T_E >$ 600 ms: ± (10 + 20% of reading) mL For neonatal circuit type setting: ± (10 + 20% of reading) mL For readings < 100 mL, the accuracy shall apply when the percentage of inspiratory leak volume is less than 80%	For adult and pediatric circuit type settings: 25 mL to 2500 mL For neonatal circuit type settings: 2 mL to 310 mL

Table 11-13. Monitoring (Patient Data) Accuracy (Continued)

Parameter	Accuracy	Range
Proximal exhaled tidal volume (V_{TEY})	± (1 + 10% of reading) mL	2 mL to 310 mL
Proximal inspired tidal volume (V_{TIY})	± (1 + 10% of reading) mL	2 mL to 310 mL
O_2% (monitored)	± 3%	15% to 100%
Respiratory rate (*f*)	± 0.8 1/min	1 1/min to 150 1/min

Table 11-14. Computed Value Accuracy

Parameter	Accuracy	Range
PAV-based lung compliance (C_{PAV})	± (1 + 20% of measured value) mL/cmH_2O	10 mL to 100 mL/cmH_2O
PAV-based total airway resistance (R_{TOT})	± (3 + 20% of measured value) cmH_2O/L/s	5.0 cmH_2O/L/s to 50 cmH_2O/L/s
PAV-based work of breathing (WOB_{TOT})	± (0.5 + 10% of measured work) J/L with a percent support setting of 75%	0.7 J/L to 4 J/L

WARNING:
The ventilator accuracies listed in this chapter are applicable under the operating conditions identified in the table *Environmental Specifications* on Reference *p. 11-7* .

Operation outside specified ranges cannot guarantee the accuracies listed in the tables above, and may supply incorrect information.

11.8 Regulatory Compliance

The ventilator complies with the following standards:

- IEC 60601-1:2005 Medical Electrical Equipment, Part 1: General Requirements for Basic safety and essential performance
- EN 60601-1:2006, Medical Electrical Equipment, Part 1: General Requirements for Basic safety and essential performance

- ANSI-AAMI ES 60601-1:2005, Medical Electrical Equipment, Part 1: General Requirements for Basic safety and essential performance
- CSA C22.2 No. 60601-1:2008 Medical Electrical Equipment, Part 1: General Requirements for Basic safety and essential performance
- IEC 60601-1-8: 2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance, Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- EN 60601-1-8:2007, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance, Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-12:2001, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance, Collateral standard: Safety requirements for medical electrical systems
- EN 60601-2-12:2005, Medical electrical equipment Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators
- ISO/EN 80601-2-12: 2011, Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- ISO 80601-2-55: 2011 and EN ISO 80601-2-55: 2012, Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors - First Edition
- ISO 5356-1:2004, Anesthetic and respiratory equipment Conical connectors Part 1: Cones and sockets
- IEC 60601-1-4:2000, Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
- IEC 60601-1-6:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62366:2007, Medical devices - Application of usability engineering to medical devices
- ANSI/AAMI HE75:2009, Human Factors Engineering - Design of Medical Devices
- IEC/EN 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 14971:2007/EN ISO 14971:2012, Medical devices - Application of risk management to medical devices

11.9 Manufacturer's Declaration

The following tables contain the manufacturer's declarations for the ventilator system electromagnetic emissions, electromagnetic immunity, separation distances between ventilator and portable and mobile RF communications equipment and a list of compliant cables.

WARNING:
Portable and mobile RF communications equipment can affect the performance of the ventilator system. Install and use this device according to the information contained in this manual.

WARNING:
The ventilator system should not be used adjacent to or stacked with other equipment, except as may be specified elsewhere in this manual. If adjacent or stacked used is necessary, the ventilator system should be observed to verify normal operation in the configurations in which it will be used.

Caution:
This equipment is not intended for use in residential environments and may not provide adequate protection to radio communication services in such environments.

Table 11-15. Electromagnetic Emissions

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the operator of the ventilator should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
Radiated RF emissions CISPR 11	Group 1 Class A	The ventilator uses RF energy only for its internal functions. The ventilator is intended to be used only in hospitals and not be connected to the public mains network.
Harmonic emissions IEC 61000-3-2	Class A	The ventilator is intended to be used only in hospitals and not be connected to the public mains network.
Voltage fluctuations/flicker IEC 61000-3-3	Complies	

Table 11-16. Electromagnetic Immunity

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the operator of the ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ± 8 kV air	±6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T(60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles < 5% U_T > 95% dip in U_T for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T(60% dip in U_T) for 5 cycles 70% U_T(30% dip in U_T) for 25 cycles < 5% U_T > 95% dip in U_T for 5 s	Mains power should be that of a typical hospital environment. If the operator of the ventilator requires continuous operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IE/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 11-16. Electromagnetic Immunity (Continued)

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the operator of the ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	1 Vrms 159 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ventilator system, including cables, than the separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 3.5\sqrt{P}$
	10 Vrms in ISM bands[1]	1 Vrms in ISM bands[1]	Recommended separation distance $d = 12\sqrt{P}$

Table 11-16. Electromagnetic Immunity (Continued)

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the operator of the ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated RF IEC/EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m Modulation of 80% AM @ 2 Hz 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the separation distance in meters (m)[2]. Field strengths from fixed transmitters, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range[4]. Interference may occur in the vicinity of equipment marked with the following symbol: 			
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 to 6,795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz; and 40.66 MHz to 40.70 MHz. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the separation distance for transmitters in these frequency ranges.

2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 980 Series Ventilator is used exceeds the applicable RF compliance level above, the 980 Series Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ventilator.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 11-17. Recommended Separation Distances for RF

The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	150 kHz to 80 MHz outside of ISM bands $d = 3.5\sqrt{P}$	150 kHz to 80 MHz inside of ISM bands $d = 12\sqrt{P}$	80MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.35	1.2	0.12	0.23
0.1	1.1	3.8	0.38	0.73
1	3.5	12	1.2	2.3
10	11	38	3.8	7.3
100	35	120	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING:
The use of accessories and cables other than those specified with the exception of parts sold by Covidien as replacements for internal components, may result in increased emissions or decreased immunity of the ventilator system.

Table 11-18.

Part number and description	Cable length
10087151, Power cord, 10A, RA, ANZ	10 ft (3 m)
10087159, Power cord, 10A, RA, UK	10 ft (3 m)
10087155, Power cord, 10A, RA, EU	10 ft (3 m)
10087157, Power cord, 10A, RA, Japan	10 ft (3 m)
10087152, Power cord, 10A, RA, British	10 ft (3 m)
10087154, Power cord, 10A, RA, Swtzrlnd	10 ft (3 m)
10081056, Power cord, 10A, RA, USA	10 ft (3 m)
10087156, Power cord, 10A, RA, Israel	10 ft (3 m)
10087160, Power cord, 10A, RA, Brazil	10 ft (3 m)
10087153, Power cord, 10A, RA, China	10 ft (3 m)

11.10Safety Tests

All safety tests should be performed by qualified Service personnel at the interval specified. Reference *Service Preventive Maintenance Frequency*, p. 1-2 in the Operator's Manual Addendum on Preventive Maintenance.

11.11Essential Performance Requirements

Per ISO/EN 80601-2-12: 2011, Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators, the ventilator's essential performance requirements are given in Ventilator Settings, Alarm Settings, and Patient Data tables earlier in this chapter. Alarms, including Oxygen level alarms and gas failure alarms, are identified in *Chapter 6*. AC and battery backup power information is given in *Chapter 3*, and gas failure cross flow information is given in *Chapter 3*.

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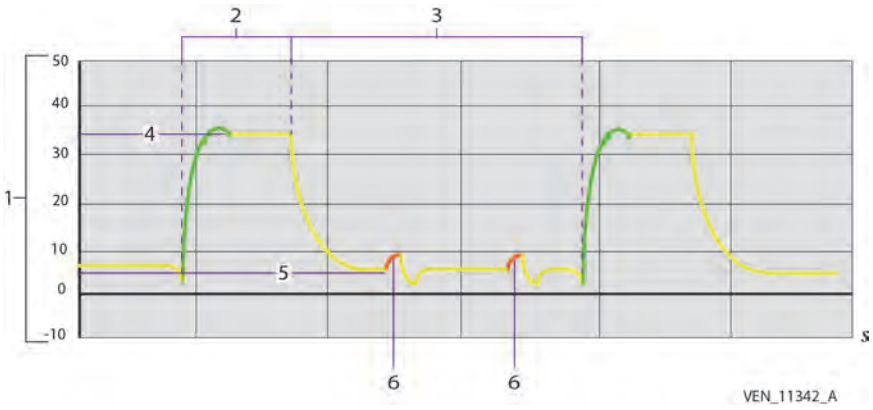
A BiLevel 2.0 Appendix

A.1 Overview

This appendix describes the operation of the BiLevel 2.0 ventilation mode on the Puritan Bennett™ 980 Series Ventilator.

BiLevel is a mixed mode of ventilation that combines attributes of mandatory and spontaneous breathing, with the breath timing settings determining which breath type is favored. In BiLevel Mode, mandatory breaths are always pressure-controlled, and spontaneous breaths can be pressure-supported (PS) or tube compensated (TC).

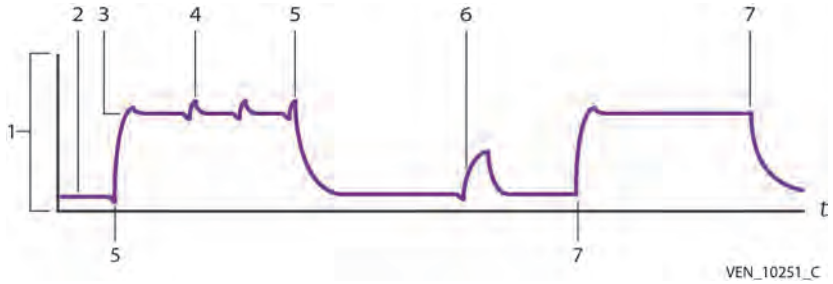
Figure A-1. Spontaneous Breathing at P_L



1	P_{CIRC} (cmH_2O)	4	P_H
2	T_H	5	P_L
3	T_L	6	Spontaneous breaths

BiLevel resembles SIMV mode, except that BiLevel establishes two levels of positive airway pressure. Cycling between the two levels can be triggered by BiLevel timing settings or by patient effort.

Figure A-2. BiLevel Mode



1	Pressure (y-axis)	5	Synchronized transitions
2	P_L	6	Pressure support
3	P_H	7	Time-based transitions
4	Spontaneous breath		NOTE: The Pressure support level is always referenced to P_L

The two pressure levels are called Low Pressure (P_L) and High Pressure (P_H). At either pressure level, patients can breathe spontaneously, and spontaneous breaths can be assisted with tube compensation or pressure support. BiLevel monitors mandatory and spontaneous tidal volumes separately.

Inspiratory time and expiratory time in BiLevel become Time high (T_H) and Time low (T_L), respectively. During these inspiratory and expiratory times, P_H is maintained during T_H and P_L is maintained during T_L.

A.2 Intended Use

BiLevel is intended for adult, pediatric, and neonatal patients.

A.3 Safety Symbol Definitions

This section contains safety information for users, who should always exercise appropriate caution while using the ventilator.

Table A-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.



WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

A.4 Setting Up BiLevel

BiLevel is a ventilatory mode (along with A/C, SIMV, and SPONT).

To set up BiLevel

1. At the ventilator setup screen, enter PBW or gender and height.
2. Touch *BiLevel*. After selecting BiLevel mode, the ventilator uses the PC mandatory breath type, which cannot be changed.
3. Choose the spontaneous type (PS or TC).
4. Choose trigger type (P_{-TRIG} or $\dot{V}_{-TRIG}$).
5. Select desired ventilator settings. The default settings for BiLevel mode appear. To change a setting, touch its button and turn the knob to set its value. P_H must always be at least 5 cmH_2O greater than P_L.

Note:
The rise time % setting determines the rise time to reach target pressure for transitions from P_L to P_H and for spontaneous breaths, even when pressure support (P_{SUPP}) = 0. Expiratory sensitivity (E_{SENS}) applies to all spontaneous breaths.

6. Set T_L, T_H, or the ratio of T_H to T_L. To select settings that would result in a T_H:T_L ratio greater than 1:1 or 4:1, you must touch *Continue* to confirm after reaching the 1:1 and 4:1 limits.

Figure A-3. BiLevel Setup Screen



7. Touch Start.

8. Set apnea and alarm settings by touching their respective tabs at the side of the ventilator settings screen and changing settings appropriately.

A.5 Using Pressure Support with BiLevel

Spontaneous breaths in BiLevel mode can be assisted with pressure support according to these rules (Reference *BiLevel with Pressure Support*, p. A-5):

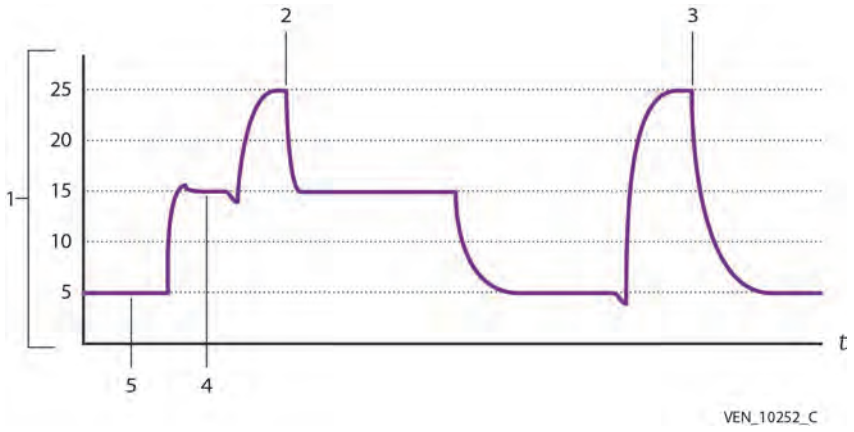
- Pressure support (P_{SUPP}) can be used to assist spontaneous breaths at P_L and P_H. P_{SUPP} is always set relative to P_L. Target pressure = P_L + P_{SUPP}.

- Spontaneous patient efforts at P_H are not pressure supported unless $P_{SUPP} > (P_H - P_L)$. All spontaneous breaths (whether or not they are pressure supported) are assisted by a pressure of 1.5 cmH_2O.
- If $P_{SUPP} + P_L$ is greater than P_H + 1.5 cmH_2O, all spontaneous breaths at P_L are assisted by the P_{SUPP} setting, and all spontaneous breaths at P_H are assisted by $P_{SUPP} - (P_H - P_L)$.
- All spontaneous breaths not supported by PS or TC (for example, a classic CPAP breath) are assisted with an inspiratory pressure of 1.5 cmH_2O.

For example, if P_L = 5 cmH_2O, P_H = 15 cmH_2O, and P_{SUPP} = 20 cmH_2O:

- All spontaneous breaths at P_L are assisted by 20 cmH_2O of pressure support ($P_L + P_{SUPP}$) for a total pressure of 25 cmH_2O, and
- All spontaneous breaths in P_H are assisted by 10 cmH_2O of pressure support ($P_{SUPP} - (P_H - P_L)$) for the same total pressure of 25 cmH_2O.

Figure A-4. BiLevel with Pressure Support



1	Pressure (y-axis)	4	P_H
2	P_H Pressure support = 10 cmH_2O	5	P_L
3	P_L Pressure support = 20 cmH_2O		

During spontaneous breaths, the pressure target is calculated with respect to P_L.

A.6 Manual Inspirations in BiLevel Mode

Pressing the MANUAL INSP key during BiLevel mode causes the ventilator to:

- Cycle to P_H, if the current pressure level is P_L.
- Cycle to P_L, If the current pressure level is P_H.

To avoid breath stacking, the ventilator does not cycle from one pressure level to another during the earliest stage of exhalation.

A.7 Respiratory Mechanics Maneuvers in BiLevel

In BiLevel, respiratory mechanics maneuvers are limited to inspiratory pause and expiratory pause maneuvers.

A.8 Specifications

Reference the table, *Ventilator Settings Range and Resolution*, in *Chapter 11* of this manual for the following specifications:

- Low pressure (P_L)
- High pressure (P_H)
- Low pressure time (T_L)
- High pressure time (T_H)
- T_H:T_L ratio
- Respiratory rate (*f*)
- Rise time %

A.9 Technical Description

BiLevel is a mode of ventilation that alternately cycles between two operator-set pressure levels, P_L and P_H. The pressure durations are defined by operator-set timing variables T_L and T_H. Transitions between the two pressure levels, P_L and P_H, are analogous to breath phase transitions in PC.

At the extreme ranges of T_L and T_H, BiLevel can resemble the single breath type mode A/C - PC, or the more complex breath type mode, an "inverted-like" IMV. If T_H and T_L assume "normal" values with respect to PBW (for example

T_H:T_L» 1:2 or 1:3), then BiLevel assumes a breathing pattern similar to, if not qualitatively identical to A/C - PC. However, as T_L begins to shorten with the T_H:T_L ratio extending beyond 4:1, the breathing pattern assumes a distinctly different shape. In the extreme, the exaggerated time at P_H and abrupt release to $P_L$would match the pattern patented by John Downs* and defined as APRV.

In between the A/C-PC-like pattern and the APRV-like pattern, there would be patterns with moderately long T_H and T_L intervals, allowing the patient sufficient time to breathe spontaneously at both P_H and P_L. In these types of breathing patterns, (but less so with APRV) BiLevel, like SIMV, can be thought of as providing both mandatory and spontaneous breath types. In this sense, BiLevel and SIMV are classified as mixed modes.

Direct access to any of the three breath timing parameters in BiLevel is accomplished by touching the Padlock icon associated with the T_H period, T_L period or the T_H:T_L ratio displayed on the breath timing bar in the setup screen.

While in BiLevel mode, spontaneously triggered breaths at either pressure level can be augmented with higher inspiratory pressures using Pressure Support (PS) or Tube Compensation (TC) breath types.

A.9.1 Synchrony in BiLevel

Just as BiLevel attempts to synchronize spontaneous breath delivery with the patient's inspiratory and expiratory efforts, it also attempts to synchronize the transitions between pressure levels with the patient's breathing efforts. This allows T_H to be extended to prevent transitions to P_L during the patient's spontaneous inspiration. Likewise, the T_L interval may be extended to prevent a transition to P_H during the patient's spontaneous exhalation.

The trigger sensitivity setting (P_{SENS} or $\dot{V}_{SENS}$) is used to synchronize the transition from P_L to P_H. The transition from P_H down to P_L is synchronized with the patient's spontaneous expiratory effort. The BiLevel algorithm will vary the T_L and T_H intervals as necessary to synchronize the transitions between P_L and P_H to match the patient's breathing pattern.

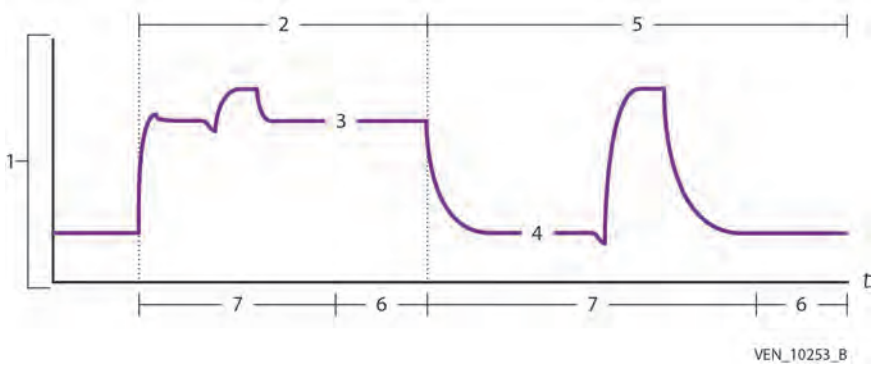
The actual durations of T_H and T_L vary according to whether or not the patient makes any spontaneous inspiratory efforts during those periods.

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*. Downs, JB, Stock MC. Airway pressure release ventilation: A new concept in ventilatory support. Crit Care Med 1987;15:459-461

To manage synchrony with the patient's breathing pattern, the BiLevel algorithm partitions the T_H and T_L periods into spontaneous and synchronous intervals as shown in the figure below.

Figure A-5. Spontaneous and Synchronous Intervals



1	Pressure (y-axis)	5	T_L
2	T_H	6	Synchronous interval
3	P_H	7	Spontaneous interval
4	P_L		

By partitioning T_H and T_L into *spontaneous* and *synchronous* phases, BiLevel responds to patient efforts (or lack of them) in a predictable pattern:

- During the *spontaneous* interval of each pressure level, successful inspiratory efforts cause the ventilator to deliver spontaneous breaths.
- During T_L *synchronous* intervals, successful inspiratory efforts cause the ventilator to cycle from P_L to P_H. If there is no spontaneous (patient) effort, this transition takes place at the end of the T_L period.
- During T_H *synchronous* intervals, successful expiratory efforts cause the ventilator to cycle from P_H to P_L. If there is no spontaneous exhalation, the transition to the P_L level takes place at the end of the T_H period.

A.9.2 Patient Monitoring in BiLevel

If the patient breathes spontaneously at either pressure level, BiLevel monitors and displays the total respiratory rate, including mandatory and spontaneous breaths. BiLevel also displays the exhaled tidal volume and total exhaled minute

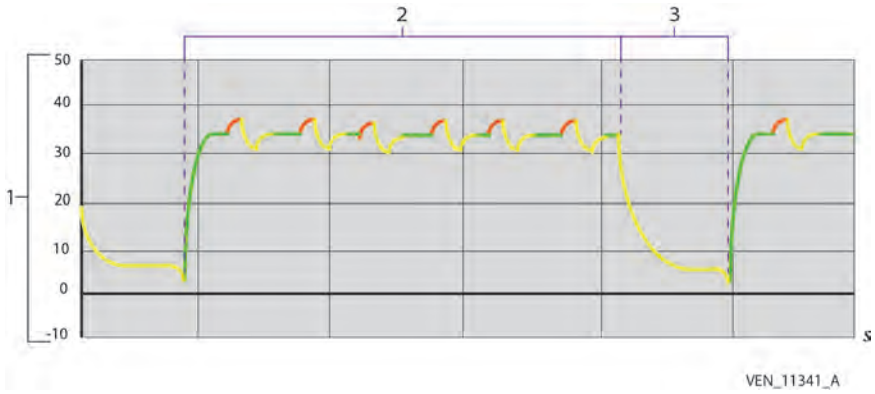
volume for both mandatory and spontaneous breaths.

A.9.3 APRV Strategy in BiLevel

Lengthening the T_H period and shortening the T_L period to only allow incomplete exhalation of the mandatory breath volume, results in an inverse T_H:T_L ratio. In this breath timing configuration with T_H:T_L ratios of greater than 4:1, BiLevel becomes **A**irway **P**ressure **R**elease **V**entilation (APRV).

APRV is characterized as longer T_H periods, short T_L periods (usually less than one second), and inverse T_H:T_L ratios. Since, at these breath timing settings, all of the patient-triggered spontaneous breaths occur during the T_H period, APRV resembles CPAP ventilation with occasional, short periods of incomplete exhalation referred to as "releases" which are controlled by the *f* setting.

Figure A-6. APRV With Spontaneous Breathing at P_H



1	P_{CIRC} (cmH_2O)	3	Shortened release time (T_L)
2	Lengthened inspiratory time (T_H)		

In APRV, the P_H level is set to optimize pulmonary compliance for spontaneous breathing while maintaining an elevated mean airway pressure to promote oxygenation, the P_L level is set, along with the T_L, to control the expiratory release volume of mandatory breaths to help manage CO_2 and alveolar ventilation, and the *f* setting controls the number of releases per minute which are used to help manage the patient's CO_2 levels. The f setting also impacts the mean airway pressure.

In APRV the operator can configure the BiLevel settings to allow direct control of T_L to assure that changes in the *f* setting will not inadvertently lengthen the T_L period resulting in destabilization of end-expiratory alveolar volume. With the T_L period locked, changes in set *f* will change the T_H period to accommodate the new *f* setting while maintaining the set T_L period.

A.9.4 Technical Structure of BiLevel

In BiLevel, the ventilator establishes two levels of baseline pressure. One level is essentially the same as the standard PEEP level set for all common modes of ventilation. The second pressure level is the level established at T_H. Both pressure levels permit CPAP, TC and PS breaths. The breath timing settings determine whether the patient can initiate any of these breath types.

A.10 Mode Changes

Changing to BiLevel mode from other modes follows the general guidelines for mode changes:

- The change is made as soon as possible without compromising inspiration or exhalation.
- Breaths are not stacked during inspiration.

B Leak Sync Appendix

B.1 Overview

This appendix describes the operation of the Puritan Bennett™ 980 Series Ventilator Leak Sync option. The Leak Sync option enables the ventilator to compensate for leaks in the breathing circuit while accurately detecting the patient's effort to trigger and cycle a breath. Because Leak Sync allows the ventilator to differentiate between flow due to leaks and flow due to patient respiratory effort, it provides dynamic compensation and enhances patient-ventilator synchrony. Reference *Chapter 4* in this manual for general parameter and operational information.

B.2 Intended Use

Leak Sync is designed to compensate for leaks in the breathing circuit during noninvasive or invasive ventilation. Leak Sync accurately quantifies instantaneous leak rates, therefore detecting patient respiratory phase transitions correctly and may affect work of breathing. Leak Sync is intended for neonatal, pediatric, and adult patients.

B.3 Safety Symbol Definitions

This section contains safety information for users, who should always exercise appropriate caution while using the ventilator.

Table B-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.



WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

B.4 Leak Sync

Breathing circuit leaks can cause the ventilator to erroneously detect patient inspiratory efforts (called autotriggering) or delay exhalation in pressure support. Patient interfaces such as masks are particularly prone to significant leaks. Inaccurately declaring inspiration or exhalation can result in patient-ventilator dysynchrony and increased work of breathing.

Changing inspiratory or expiratory sensitivity settings can temporarily correct the problem, but requires continued frequent clinical intervention to ensure that sensitivity is adjusted appropriately as conditions change (for example, if the patient moves or the circuit leak changes).

Leak Sync adds flow to the breathing circuit to compensate for leaks. The maximum Leak Sync flow applies to the maximum base flow compensation during exhalation. During pressure-based inspirations, the total delivered flow (leak flow plus inspiratory flow) is limited by the maximum total flow.

The following table shows the maximum leak rates at set PEEP pressure that Leak Sync will compensate based on patient type.

Table B-2. Leak Compensation Volumes Based on Patient Type

Patient type	Maximum Leak compensation flow
Neonatal	15 L/min
Pediatric	40 L/min
Adult	65 L/min

B.5 Setting Up Leak Sync

For more information on setting up the ventilator, Reference *Chapter 4* of this manual.

To enable Leak Sync

1. At the ventilator setup screen, touch the More Settings tab.
2. Touch *Enabled* in the Leak Sync area.
3. Touch *Accept ALL* to enable Leak Sync.

Figure B-1. Enabling Leak Sync



Note:
The default value for Leak Sync is **Disabled** when the circuit type is Pediatric or Adult and the Vent Type is Invasive. Otherwise the default value for Leak Sync is **Enabled**.

Note:
Leak Sync is not allowed for tube compensated (TC) and Proportional Assist Ventilation (PAV+) breath types.

B.6 When Leak Sync is Enabled

Reference *GUI Screen when Leak Sync is Enabled*, p. B-5 for an example showing the GUI screen when Leak Sync is enabled.

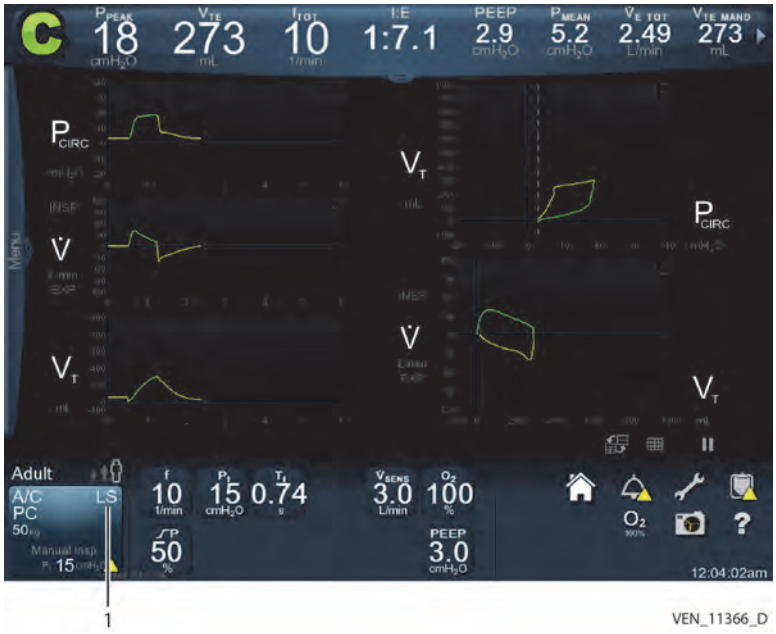
- The Vent Setup button on the GUI screen indicates Leak Sync is active.
- D_{SENS} is displayed in units of L/min, rather than %.
- If the ventilator detects a leak during a respiratory mechanics maneuver, the message Leak Detected is displayed.
- A new leak or change in leak rate is typically quantified and compensated within three breaths. Monitored patient data stabilizes within a few breaths.

- Select inspiratory and expiratory sensitivity settings as usual. If the ventilator auto-triggers, try increasing flow sensitivity ($\dot{V}_{SENS}$)

Note:
The absence of the Leak Detected message does not mean there is no leak.

Note:
Leak Sync is automatically enabled when ventilating a new patient and the circuit type is neonatal, regardless of the Vent Type. If Leak Sync is disabled, it remains disabled when switching between INVASIVE and NIV Vent Types.

Figure B-2. GUI Screen when Leak Sync is Enabled



1 LS appears on Vent Setup button notifying the operator that Leak Sync is enabled

B.6.1 Adjusting Disconnect Sensitivity (D_{SENS})

When Leak Sync is enabled, the Circuit Disconnect alarm becomes active based on the D_{SENS} setting, which is the maximum allowable leak rate at set PEEP.

When Leak Sync is disabled, D_{SENS} is automatically set to 75%.

WARNING:
When Vent Type = NIV and Leak Sync is disabled, D_{SENS} is automatically set to OFF.

Reference the table below for a summary of D_{SENS} settings when Leak Sync is enabled. Note that it is possible to set D_{SENS} below maximum Leak Sync flow.

Table B-3. D_{SENS} settings

Breathing circuit type	D_{SENS} setting	Maximum total flow
Neonatal	Range: 1 to 15 L/min Default: 2 L/min (INVASIVE ventilation) 5 L/min (NIV)	50 L/min
Pediatric	Range: 1 to 40 L/min Default: 20 L/min	120 L/min
Adult	Range: 1 to 65 L/min Default: 40 L/min	200 L/min

WARNING:
With significant leaks, pressure targets may not be reached due to flow limitations.

WARNING:
Setting D_{SENS} higher than necessary may prevent timely detection of inadvertent extubation.

B.6.2 Monitored Patient Data

When Leak Sync is enabled, three additional parameters are displayed on the More Patient Data screen and updated for each breath. Display the More Patient Data screen by swiping the tab on the patient data banner. These leak parameters may also be configured on the patient data banner and the large font patient data panel.

Figure B-3. Leak Sync Monitored Patient Data



1 Leak Sync Parameters

Reference the table *Patient Data Range and Resolution* in *Chapter 11* of this manual for information regarding the following monitored patient data parameters:

- V_{LEAK}
- % LEAK
- LEAK

Displayed values for Exhaled Tidal Volume (V_{TE}) and Inspired Tidal Volume (V_{TL}) are leak-compensated, and indicate the estimated inspired or exhaled lung volume. The accuracies for V_{TE} and V_{TL} also change when Leak Sync is enabled (see Technical Discussion for more information). Graphic displays of flow during Leak Sync indicate estimated lung flows.

B.7 Technical Discussion

Managing breathing circuit leaks is important to ensure appropriate breath triggering and cycling, ventilation adequacy, and valid patient data. Detecting and monitoring leaks can improve treatment, reduce patient work of breathing, and provide more accurate information for clinical assessments.

Leak Sync recognizes that changing pressures lead to varying deflection of interface materials and leak sizes. The Leak Sync leak model includes a rigid leak orifice whose size remains constant under changing pressures, combined with an elastic leak source whose size varies as a function of applied pressure. This algorithm provides a more accurate estimate of instantaneous leak to improve patient-ventilator synchrony under varying airway pressures.

Leak Sync allows the ventilator to determine the leak level and allows the operator to set the flow trigger and peak flow sensitivities to a selected threshold. The base flow during exhalation is set to:

- Flow triggering: 1.5 L/min + estimated leak flow at PEEP + flow sensitivity.
- Pressure triggering: 1.0 L/min + estimated leak flow at PEEP.

B.7.1 Inspired Tidal Volume (V_{TL}) Accuracy During Leak Sync

Reference *Patient Data Range and Resolution*, p. 11-19, V_{TL} parameter, for V_{TL} accuracy.

For readings < 100 mL, accuracy ranges apply when the percentage of inspiratory leak volume is < 80%, where the percentage of leak volume is:

(Leak volume during inspiration / total delivered inspiratory volume) x 100

Note:
Inspired tidal volume is labeled as V_{TL} when Leak Sync is enabled, and as V_{TI} when Leak Sync is disabled.

B.7.2 Exhaled Tidal Volume (V_{TE}) Accuracy During Leak Sync

Reference *Patient Data Range and Resolution*, p. 11-19, V_{TE} parameter, for accuracy when Leak Sync is enabled.

where T_E = time to exhale 90% of volume actually exhaled by the patient.

For readings < 100 mL, accuracy ranges apply when the percentage of inspiratory leak volume is < 80%, where the percentage of leak volume is:

(Leak volume during inspiration/total delivered inspiratory volume) x 100

B.7.3 %LEAK Calculation

Reference *Patient Data Range and Resolution*, p. 11-19, % LEAK parameter, for specifications.

B.7.4 Circuit Disconnect Alarm During Leak Sync

The Circuit Disconnect alarm is activated if the overall leak volume during the whole breath exceeds the maximum leak volume derived from the D_{SENS} setting. During VC, the Circuit Disconnect alarm is also activated if the end-inspiratory pressure falls below (set PEEP + 1 cmH_2O) for three consecutive breaths. The screen shows this alarm message:

Figure B-4. Circuit Disconnect During VC



Normal operation resumes if the ventilator detects a patient connection.

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C IE Sync Appendix

C.1 Overview

This appendix describes the operation of the Puritan Bennett™ 980 Ventilator IE Sync option.

When a mechanically ventilated patient is capable of some degree of ventilatory effort, it is essential that the ventilator be as responsive as possible to the patient's efforts. In most modes and breath types, this is done by clinicians estimating P_{SENS}, $\dot{V}_{SENS}$, and E_{SENS}.

IE Sync is a ventilator triggering and cycling algorithm based on real-time estimation of the patient's intra-pleural pressure. The algorithm processes ventilator pressure and flow measurements in a way that accounts for the variability of respiratory parameters of the patient population. In a bench-top model simulating patients with flow limitation, incomplete exhalation or weak spontaneous efforts, IE Sync triggering has been shown to decrease the number of missed breaths when compared to flow triggering.

C.2 Intended Use

IE Sync is intended for invasively ventilated, spontaneously breathing pediatric and adult patients, only, and not for neonatal patients.

C.3 Safety Symbol Definitions

This section contains safety information for users, who should always exercise appropriate caution while using the ventilator.

Table C-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.



WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

C.4 IE Sync Description

IE Sync is a triggering and cycling algorithm based on the estimated patient intra-pleural pressure. It is only available in SPONT mode, with the following breath types: PAV+, PS, VS, and TC. A PBW ≥ 25 kg is recommended. IE Sync can also be used in monitoring mode, where it does not control the patient's breath triggering and cycling, but only indicates where in the patient's breath cycle an inspiration and expiration would have started if IE Sync were active.

C.5 Setting Up IE Sync

To set up IE Sync

1. At the ventilator setup screen, enter the patient’s gender and height or PBW.
2. Touch the Invasive vent type button.

3. Touch SPONT mode.
4. Touch PAV+, VS, PS, or TC to choose the spontaneous type.
5. Touch IE Sync as the trigger type.
6. Set the inspiratory triggering threshold (I_{SENS}).
7. Set the expiratory sensitivity threshold (E_{SENS}).
8. Continue setting up the ventilator as described in *Chapter 4* of this manual.

Figure C-1. Setup Screen



Note:
If Leak Sync is currently enabled, it becomes disabled when IE Sync is selected as the trigger type. Leak Sync cannot be selected if using IE Sync as the trigger type. Conversely, If IE Sync is disabled, then Leak Sync becomes selectable.

A message appears on the GUI stating "IE Sync Startup" until the IE Sync startup period completes. The startup period takes three (3) breaths to reach a steady state, after which it triggers and cycles the ventilator breaths. During the startup period, the default ventilator settings are:

- Trigger type — P_{-TRIG}
- P_{SENS} — 2 cmH_2O

- E_{SENS} — 25% if IE Sync has not been used previously, otherwise default E_{SENS} setting for the currently active breath type

If IE Sync is enabled while in transition from a different trigger type, then the trigger type, P_{SENS}, and E_{SENS} settings from the prior breath type shall be used during startup instead of those stated above.

C.6 Setting Up IE Sync for Monitoring Only

To set up IE Sync for monitoring only:

1. At the Vent Setup screen, change the trigger type to a type other than IE Sync.
2. Touch "*Accept*".
3. Swipe the *Menu* tab on the left side of the GUI.

Figure C-2. Monitoring Setup



4. Touch *IE Sync*. A dialog appears allowing enabling (ON) or disabling (OFF) of IE Sync monitoring.

Figure C-3. Monitoring Dialog



5. Touch *ON*.
6. Set the inspiratory trigger threshold (I_{SENS}).
7. Set the expiratory sensitivity threshold (E_{SENS}).
8. Touch *Close*.

C.7 IE Sync Monitoring Display

The waveforms screen shows the P_{SYNC} (intra-pleural pressure) signal and the I:E signal during the delivery of a spontaneous breath. Reference *Technical Description*, p.C-7 for details regarding P_{SYNC}.

Note:
IE Sync-related signals are not displayed during Apnea ventilation.

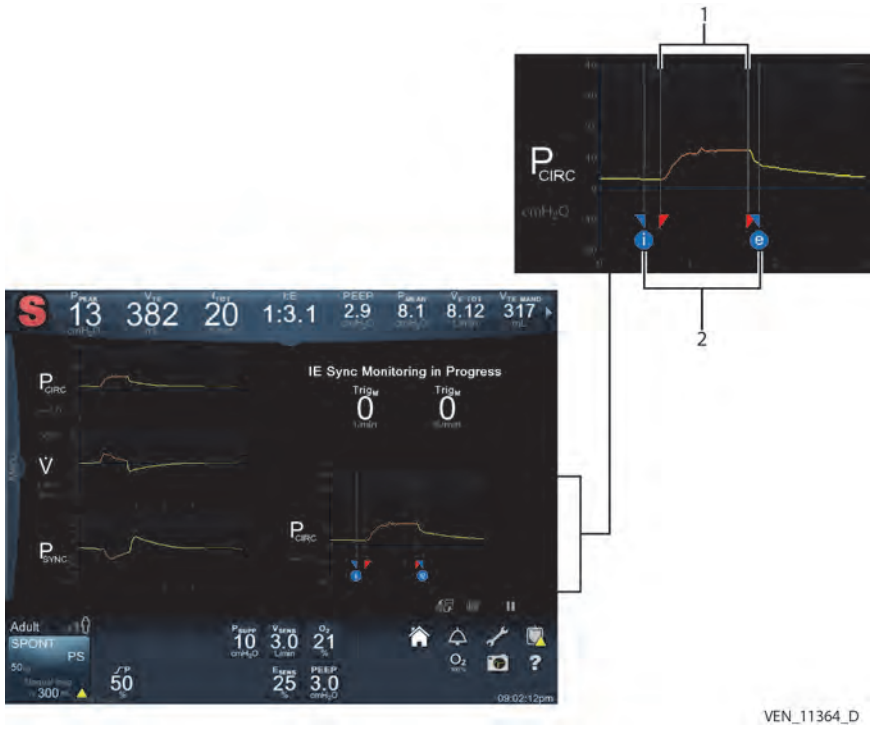
IE Sync monitoring displays a waveform indicator marking where in the breath cycle the ventilator would have triggered an inspiration or expiration and started an expiration if IE Sync were in use.

When using IE Sync monitoring, the waveform displays an indication of missed breath triggers, if applicable (missed triggers per minute and the percent of missed triggers).

Note:
IE Sync-related signals are not displayed during Apnea ventilation.

When using IE Sync monitoring, the screen appears as shown below.

Figure C-4. Monitoring Waveform



1 The points at which the actual inspiration and expiration took place under pressure trigger or flow trigger

2 I:E signal: The points in the breath where IE Sync would have triggered an inspiration and expiration if not in monitoring

Note:
In the P_{CIRC} waveform above, red indicates the current breath trigger and cycle timing, and blue indicates where IE Sync would have triggered inspiration and exhalation, had IE Sync been the chosen trigger type.

C.8 Technical Description

IE Sync uses a real-time estimate, $\hat{\dot{p}}_{P}$ (P_{SYNC}), of the time-derivative of intra-pleural pressure for determining breath phase transitions. P_{SYNC} is computed every five (5) *ms* based on a proprietary algorithm that uses the ventilator's pressure and flow sensor readings as its inputs. IE Sync detects the start of inspiration when P_{SYNC} reaches the set I_{SENS} threshold, and detects the end of inspiration when the P_{SYNC} signal reaches the set E_{SENS} threshold.

C.9 Alarms during IE Sync

If an alarm occurs during IE Sync which causes the ventilator to enter inspiratory or expiratory Back Up Ventilation (BUV), the trigger type automatically changes to the factory default trigger type, which can be institutionally configured. If and when the alarm that caused BUV is corrected, IE Sync will not automatically be re-enabled; if IE Sync is still desired, then the user must re-enable it.

An apnea condition during IE Sync causes the trigger type to change to P_{-TRIG} with P_{SENS} of two (2) cmH_2O.

IE Sync breaths go through a startup period when normal ventilation resumes after the following resets:

- Circuit occlusion
- Circuit disconnect
- Loss of both gas supplies (SVO)
- Calculated lung compliance value is invalid
- Calculated patient resistance value is invalid

If there are five (5) internal resets in a 20-minute period, IE Sync will automatically become disabled, and will be set to $\dot{V}_{-TRIG}$ with new-patient default sensitivities. Reference the table *Ventilator Settings Range and Resolution* in *Chapter 11* of this manual. A message displays on the GUI if IE Sync becomes disabled due to internal resets, and the unread items icon appears on the ventilator setup dialog.

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D PAV™+ Appendix

D.1 Overview

This appendix describes the operation of the PAV™* + software option for the Puritan Bennett™ 980 Ventilator.

Proportional Assist™* Ventilation (PAV+) is designed to improve the work of breathing of a spontaneously breathing patient by reducing the patient's increased work of breathing when pulmonary mechanics are compromised.

The PAV+ breath type differs from the pressure support (PS) breath type in the following way:

PAV+ acts as an inspiratory amplifier; the degree of amplification is set by the % Support setting (% Supp). PAV+ software continuously monitors the patient's instantaneous inspiratory flow and instantaneous lung volume, which are indicators of the patient's inspiratory effort. These signals, together with ongoing estimates of the patient's resistance and compliance, allow the software to instantaneously compute the necessary pressure at the patient wye to assist the patient's inspiratory muscles to the degree selected by the % Supp setting. Higher inspiratory demand yields greater support from the ventilator.

PAV+ software reduces the risk of inadvertent entry of incompatible settings, such as small predicted body weight (PBW) paired with a large airway.

D.2 Intended Use

PAV+ is intended for use in spontaneously breathing adult patients whose ventilator predicted body weight (PBW) setting is at least 25.0 kg (55 lb). Patients must be intubated with either endotracheal (ET) or tracheostomy (Trach) tubes of internal diameter (ID) 6.0 mm to 10.0 mm. Patients must have satisfactory neural-ventilatory coupling, and stable, sustainable inspiratory drive.

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*. Proportional Assist and PAV are registered trademarks of The University of Manitoba, Canada. Used under license.

D.3 Safety Symbol Definitions

This section contains safety information for users, who should always exercise appropriate caution while using the ventilator.

Table D-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.



WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.



WARNING:
PAV+ is not an available breath type in non-invasive ventilation (NIV). Do not use non-invasive patient interfaces such as masks, nasal prongs, uncuffed ET tubes, etc. as leaks associated with these interfaces may result in over-assist and patient discomfort.



WARNING:
Breathing circuit and artificial airway must be free from leaks. Leaks may result in ventilator over-assist and patient discomfort.

WARNING:
Ensure high and low tidal volume alarm thresholds are set appropriately because an overestimation of lung compliance could result in an under-support condition resulting in the delivery of smaller than optimal tidal volumes.

D.4 PAV+

WARNING:
Ensure that there are no significant leaks in the breathing circuit or around the artificial airway cuff. Significant leaks can affect the performance of the PAV+ option and the accuracy of resistance (R) and elastance (E) estimates.

WARNING:
Do not use silicone breathing circuits with the PAV+ option: the elastic behavior of a silicone circuit at the beginning of exhalation can cause pressure-flow oscillations that result in underestimates of patient resistance.

The act of inspiration requires the patient's inspiratory muscles to develop a pressure gradient between the mouth and the alveoli sufficient to draw in breathing gas and inflate the lungs. Some of this pressure gradient is dissipated as gas travels through the artificial airway and the patient's conducting airways, and some of the pressure gradient is dissipated in the inflation of the lungs and thorax. Each element of pressure dissipation is characterized by a measurable property: the resistance of the artificial and patient airways, and the compliance (or elastance) of the lung and thorax.

PAV+ software uses specific information, including resistance of the artificial airway, resistance of the patient's airways, lung-thorax compliance, instantaneous inspiratory flow and lung volume, and the % Supp setting to compute the instantaneous pressure to be applied at the patient connection port (patient wye). PAV+ software randomly estimates patient resistance and compliance approximately every four to ten breaths. Every five (5) ms, the software estimates lung flow, based on an estimate of flow at the patient wye, and lung volume, based on the integral of the value of estimated lung flow.

PAV+ begins to assist an inspiration when flow (generated by the patient's inspiratory muscles) appears at the patient wye. If the patient ceases inspiration, the assist also ceases. Once inspiratory flow begins, PAV+ software monitors instantaneous flow and volume every 5 ms and applies the pressure

calculated to overcome a proportion (determined by the % Supp setting) of the pressure losses dissipated across the resistances of the artificial and patient airways and lung/thorax compliance.

Because the PAV+ algorithm does not know the patient's mechanics when the PAV+ breath type is selected, the software performs a startup routine to obtain initial data. At startup, PAV+ software delivers four consecutive PAV+ breaths, each of which includes an end-inspiratory pause maneuver that yields estimates of the patient's resistance and compliance. The first breath, however, is delivered using the predicted resistance for the artificial airway and conservative estimates for patient resistance and compliance, based on the patient's PBW.

Each of the next three PAV+ breaths averages stepwise decreased physiologic values with the estimated resistance and compliance values from the previous breath, weighting earlier estimates less with each successive breath, and yielding more reliable estimates for resistance and compliance. The fifth PAV+ breath (the first non-startup breath) is delivered using the final estimates with the clinician-set % Supp setting. Once startup is complete, the PAV+ software randomly applies a maneuver breath every four to ten breaths after the last maneuver breath to re-estimate patient resistance and compliance. New values are always averaged with former values.

The PAV+ option graphically displays estimates of patient lung pressure (intrinsic PEEP), patient compliance, patient resistance, total resistance, total work of inspiration, patient work of inspiration, inspiratory elastic work (an indicator of lung-thorax work), and inspiratory resistive work.

The % Supp setting ranges from a minimum of 5% (the ventilator performs 5% of the work of inspiration and the patient performs 95%) to a maximum of 95% (the ventilator performs 95% of the work and the patient performs 5%), adjustable in 5% increments.

The PAV+ option also includes alarm limits, safety checks, and logic checks that reject non-physiologic values for patient resistance and compliance as well as inappropriate data.

Humidification type and volume can be adjusted after running SST, however the ventilator makes assumptions when calculating resistance and compliance if these changes are made without re-running SST. For optimal breath delivery, run SST after changing humidification type and humidifier volume.

D.4.1 Setting Up PAV+

To set up PAV+

1. At the ventilator setup screen, enter the patient's gender and height or the patient's PBW.
2. Touch INVASIVE vent type.
3. Touch SPONT mode.
4. Touch PAV+ to select Spontaneous type.
5. Touch the desired trigger type (P_{-TRIG}, V_{-TRIG}, or IE Sync (if the IE Sync option is installed).
6. Select tube type
7. Select the tube ID. Initially, a default value is shown based on the PBW entered at ventilator startup. If this ID is not correct for the airway in use, turn the knob to adjust the ID setting.

Note:
If the operator selects an internal diameter that does not correspond to the PBW/tube ID range pairs listed in the following table, touch the continue button to override the tube ID setting. If attempts are made to choose a tube ID less than 6.0 mm or greater than 10 mm, a hard bound limit is reached, as PAV+ is not intended for use with tubes smaller than 6.0 mm or larger than 10.0 mm. When touching *Dismiss*, the setting remains at the last tube ID selected. Touch *Accept* or *Accept ALL* to accept changes, or touch *Cancel* to cancel changes.

8. Continue setting up the ventilator as described in *Chapter 4* of this manual.

Note:
If Leak Sync is currently enabled, it becomes disabled when PAV+ is selected.

Figure D-1. Ventilator Setup Screen



Note:
When the ventilator is used on the same patient previously ventilated using PAV+, the GUI displays an attention icon and the tube type and tube ID previously used, as a reminder to the clinician to review those settings during ventilator setup.

D.4.2 PBW and Tube ID

The ventilator uses "soft bound" and "hard bound" values for estimated tube inside diameters based upon PBW. Soft bounds are ventilator settings that have reached their recommended high or low limits. When adjusting the tube size, if the inside diameter does not align with a valid predicted body weight, a *Continue* button appears. Setting the ventilator beyond these soft bounds requires the operator to acknowledge the prompt by touching *Continue* button before continuing to adjust the tube size. The limit beyond which the tube ID cannot be adjusted is called a hard bound, and the ventilator emits an invalid entry tone when a hard bound is reached.

WARNING:
Ensure that the correct artificial airway ID size is entered. Because PAV+ amplifies flow, entering a smaller-than-actual airway ID causes the flow-

based pressure assistance to over-support the patient and could lead to transient over-assist at high values of % Supp. Conversely, entering a larger-than-actual ID results in under-support. PAV+ software monitors the settings for the PBW and artificial airway. If the PBW and tube ID settings do not correspond to the above PBW/tube ID range pairs, confirm or correct the settings. Confirming or correcting the actual ID size minimizes the likelihood that PAV+ will over-support or under-support.

To apply new settings for the artificial airway follow these steps



1. Touch *Vent Setup* at the lower left of the GUI screen.
2. Touch Tube Type and turn the knob to select Trach or ET to set the tube type.
3. Touch tube ID and turn the knob to set the tube ID.
4. Touch *Accept* or *Accept ALL* to apply the new settings, or *Cancel* to cancel.

To apply new humidifier settings

1. Touch the More Settings tab.
2. Touch the appropriate button for Humidification Type.
3. For non-HME humidification types, touch *Humidifier Volume*, then turn the knob to adjust the (empty) humidifier volume.
4. Touch *Accept ALL* to apply the changes.

WARNING:
To ensure the accuracy of PAV+ breaths and spirometry measurements, run SST following any change to the humidification type or humidification volume settings. Ensure that the intended circuit is used with the SST.

D.4.3 Apnea Parameters Adjustment

After accepting the PAV+ settings, touch the Apnea Setup screen. Adjust the Apnea parameters as required.

D.4.4 Alarm Settings Adjustment

PAV+ includes the high inspired tidal volume ($\uparrow V_{TI}$) and low exhaled spontaneous tidal volume alarm ($\downarrow V_{TE\ SPONT}$) alarm limit settings. Reference *PAV+ Alarms*, p. D-10.

Note:
Because of the breathing variability that PAV+ allows, the $\downarrow V_{TE\ SPONT}$ alarm, by default, is turned OFF to minimize nuisance alarms. To monitor adequate ventilation, use the $\downarrow \dot{V}_{E\ TOT}$ alarm condition instead.

To adjust alarm settings

1. Touch the Alarm tab to view the current alarm settings.
2. Touch the button for each alarm limit requiring a change.
3. Turn the knob to adjust the value of the alarm limit. Proposed values are highlighted. You can change more than one alarm limit before applying the changes.
4. Touch *Accept* or *Accept All* to apply the changes, or Cancel to cancel.

D.4.5 PAV+ Ventilator Settings

Reference the table *Ventilator Settings Range and Resolution*, in *Chapter 11* of this manual for a summary of PAV+ ventilator settings for the following parameters:

- $\%_{\ Supp}$
- Expiratory sensitivity (E_{SENS})
- Tube type
- Tube ID
- Trigger type

D.4.6 PAV+ Alarm Settings

Reference the table *Alarm Settings Range and Resolution*, in *Chapter 11* of this manual for a summary of the following alarm settings available when PAV+ is active:

- High inspired tidal volume limit ($\uparrow V_{TI}$)
- Low exhaled spontaneous tidal volume ($\downarrow V_{TE\ SPONT}$)

D.4.7 Monitored Data

Reference *Patient Data Range and Resolution*, in *Chapter 11* of this manual for the following monitored data associated with PAV+:

- PAV-based lung compliance (C_{PAV})
- PAV-based lung elastance (E_{PAV})
- PAV-based lung resistance (R_{PAV})
- PAV-based total airway resistance (R_{TOT})
- Inspired tidal volume (V_{TI})

Reference the table below for monitored data absolute limits.

Table D-2. Absolute limits for PAV+ Monitored Data

PBW (kg)	R_{PAV} ($cmH_2O/L/s$)	C_{PAV} (mL/cmH_2O	E_{PAV} (cmH_2O/L
25	0 to 50	2.5 to 29	34 to 400
35	0 to 44	3.5 to 41	24 to 286
45	0 to 31	4.5 to 52	19 to 222
55	0 to24	5.5 to 64	16 to 182
65	0 to 20	6.4 to 75	13 to 156
75	0 to 18	7.4 to 87	11 to 135
85	0 to 17	8.4 to 98	10 to 119
95	0 to 16	9.4 to 110	9.1 to 106
105	0 to 15	10 to 121	8.3 to 100
115	0 to 15	11 to 133	7.5 to 91
125	0 to 14	12 to 144	6.9 to 83
135	0 to 14	13to 156	6.4 to 77
145	0 to 14	14 to 167	6.0 to 71
150	0 to 14	15 to 173	5.8 to 67

D.4.8 PAV+ Alarms

Reference *Non-technical Alarm Summary* in *Chapter 6* of this manual for a summary of the following alarms associated with PAV+:

- High circuit pressure ($\uparrow P_{PEAK}$)
- High ventilator pressure($\uparrow P_{VENT}$)
- PAV STARTUP TOO LONG
- PAV R&C NOT ASSESSED
- $\uparrow V_{TI}$

D.5 Ventilator Settings/Guidance

WARNING:
For optimal performance of PAV+, it is important to select the humidification type, tube type, and tube size that match those in use on the patient.

The instantaneous pressure generated at the patient wye during inspiration is a function of the patient effort, % Supp setting, tube type and size, patient resistance and elastance, and the instantaneously measured gas flow and lung volume. Set $\overline{\uparrow} P_{PEAK}$ to a safe circuit pressure, above which truncation and alarm annunciation are appropriate.

Note:
PAV+ has a built-in high pressure compensation ($\uparrow P_{COMP}$) limit that is determined by the$\overline{\uparrow} P_{PEAK}$ setting minus 5 cmH_2O or 35 cmH_2O, whichever is less. If the inspiratory pressure at the patient wye ($P_{I\ wye}$) reaches the $\uparrow P_{COMP}$ limit, the inspiration is truncated, and the ventilator transitions to exhalation. Reference *p. D-21* for more details regarding $\uparrow P_{COMP}$ and $\uparrow P_{PEAK}$.

D.5.1 Specified performance

Performance using PAV+ is ± 0.5 Joules/liter (J/L), compared to measured, work during inspiration at the 75% support (% Supp) level. Work is computed over the entire inspiratory interval. In ventilation terms, work (W) is expressed as:

$$W = \frac{k \times \int (P^i \times \dot{V}^i) dt}{\int \dot{V}^i dt}$$

i	ith sample interval (5 ms)	$\dot{V}$	Flow [L/s]
W	Work [J/L]	k	conversion constant (0.098) [J/cmH_2O x L)
P	Synchronous and combined pressures developed by the ventilator and by the patient (P_{MUS}), [cmH_2O]		

D.5.2 Graphics Displays in PAV+

When PAV+ is active (the mode is SPONT and the spontaneous breath type is PAV+), a work of breathing (WOB) graphic is automatically displayed (Reference *Graphics displays in PAV+*, p. D-14) which shows:

- estimates of work of breathing relative to normal, subnormal, and above-normal values, including:
  - the estimated work of breathing in Joules/L) during inspiration (WOB_{PT}) and
  - the estimated total work of breathing (in Joules/L) of the patient and ventilator during inspiration (WOB_{TOT})

- an indicator showing the proportion of patient inspiratory work to overcome the elastance (E) of the lung-thorax and the combined resistance (R) of the artificial airway and the patient.

Additional information in the graphics screen includes

- a "shadow" trace of the estimated lung pressure, shown as a solid area superimposed on the circuit pressure waveform.
- PAV-based patient data estimates, including patient resistance (R_{PAV}), lung compliance (C_{PAV}), and intrinsic PEEP ($PEEP_{I\ PAV}$).

Note:
Graphic displays of lung pressure and patient work of breathing are not actual measurements, and are derived from equations using filtered estimates of pressure and flow.

The WOB graphic is only available when SPONT mode and the PAV+ breath type are selected. The shadow trace can be enabled or disabled when selecting the graphic display, or after a display is paused.

The act of pausing does not affect the WOB graphic, but does store the shadow trace. Once paused, the operator can enable or disable the shadow trace, then view the paused waveform again with or without the shadow trace.

D.5.3 WOB Terms and Definitions

The following table provides a definition and description of each of the Work of Breathing (WOB) terms.

Table D-3. PAV+ Work of Breathing terms

WOB term	Definition	Description
WOB_{TOT}	Total Work of Inspiration	With the PAV+ breath type active, the patient and the ventilator always share the in the work of breathing. The percent WOB_{TOT} performed by the ventilator always equals the % Supp setting and the percent WOB_{TOT} performed by the patient always equals (100 minus the % Supp setting). WOB_{TOT} is the sum of the work to move the breathing gas through the artificial airway and the patient's own airways plus the work to inflate the patient's elastic lung-thorax.
WOB_{PT}	Patient Work of Breathing	That part of WOB_{TOT} performed by the patient.
$WOB_{PT\ ELASTIC}$	Inspiratory Elastic Work	That part of WOB_{PT} attributed to inflating the patient's elastic lung-thorax.
$WOB_{PT\ RESISTIVE}$	Inspiratory Resistive Work	That part of the WOB_{PT} attributed to moving breathing gas through resistive elements in the gas path.

Figure D-2. Graphics displays in PAV+



1	Total work of breathing (WOB_{TOT})	3	Shadow trace
2	Patient's work of breathing (WOB_{PT})		

D.5.4 Technical Description

When PAV+ is selected, the ventilator acts as an inspiratory amplifier, proportionally assisting the pressure generating capability of the inspiratory muscles (P_{MUS}).

Pressure Gradient Equation of Motion

During spontaneous breathing, P_{MUS} generates a pressure gradient that drives breathing gas through the artificial airway and the patient's airways and into the elastic lung-thorax, and is described by the equation of motion:

EQUATION 1

$$P_{MUS} = \dot{V}_L \times R + V_L \times E_{LUNG-THORAX}$$

P_{MUS}	Pressure generating capability of patient's inspiratory muscles	R	Resistance elements (artificial plus patient airways)
$\dot{V}_L$	Flow through the resistance elements and into the lungs	$E_{LUNG-THORAX}$	Elastance of the lung and thorax ($1/C_{LUNG-THORAX}$)
V_L	Insufflation volume of the lung		

Estimates of Patient Resistance and Elastance

If the PAV+ software estimates of patient resistance and elastance (R_{PAV} and (E_{PAV}) remain stable, this equation could be rewritten as:

EQUATION 2

$$P^{i}_{MUS} = \dot{V}^{i}_{L} \times R^{i}_{airway} + \dot{V}^{i}_{L} \times K_1 + V^{i}_{L} \times K_2$$

i	Instantaneous value of pressure, flow, or airway resistance, R^{i}_{airway} being a function of flow	K_1	R_{PAV}
K_2	E_{PAV}		

P^{i}_{MUS} could then be estimated at every control period if $\dot{V}^{i}_{L}$, R^{i}_{airway}, and V^{i}_{L} were also known.

Valid Individual Pressure Measurements

Throughout any inspiration, the individual pressure elements that make up P_{MUS} can be expressed as:

EQUATION 3

$$p_{MUS} = P^{FLOW}_{ARTIFICIAL\ AIRWAY} + P^{FLOW}_{PATIENT} + P^{VOLUME}_{PATIENT}$$

P_{MUS}	Pressure generating capability of patient's inspiratory muscles	$P^{FLOW}_{PATIENT}$	Flow based pressure drop across the patient
$P^{FLOW}_{ARTIFICIAL\ AIRWAY}$	Flow based pressure drop across the artificial airway	$P^{VOLUME}_{PATIENT}$	Volume based pressure to overcome the lung-thorax elastance

Equations 2 and 3 provide the structure to explain how PAV+ operates. The clinician enters the type and size of artificial airway in use, and the software uses this information to estimate the resistance of the artificial airway at any lung flow.

Applying a special pause maneuver at the end of selected inspirations provides the information the software needs to estimate patient resistance (R_{PAV}) and compliance (C_{PAV}, which is converted to elastance, E_{PAV}). Immediately following the end of the pause event, software captures simultaneous values for P_{LUNG}, P_{wye}, and $\dot{V}_E$ which yield an estimate for R_{TOT} at the estimated flow.

All raw data are subjected to logic checks, and the estimates of R_{PAV} and C_{PAV} are further subjected to physiologic checks. The estimates of R_{PAV} and C_{PAV} are discarded if any of the logic or physiologic checks fail. If C_{PAV} is rejected, R_{PAV} is also rejected.

Valid estimates of R_{PAV} and C_{PAV} are required for breath delivery, and are constantly updated by averaging new values with previous values. This averaging process smooths data and avoids abrupt changes to breath delivery. If new values for R_{PAV} and C_{PAV} are rejected, the previous values remain active until valid new values are obtained. PAV+ software monitors the update process and generates an escalating alarm condition if the old values do not refresh.

Maneuver Breaths and % Supp

During PAV+, maneuver breaths are randomly performed every four to ten breaths after the last maneuver breath. A maneuver breath is a normal PAV+ inspiration with a pause at end inspiration. Because muscle activity is delayed for at least 300 ms following the end of neural inspiration, the patient's respiratory control center does not detect the pause. With this approach, maneuver breaths are delivered randomly so that their occurrence is neither consciously recognized nor predictable.

A PAV+ breath begins, after the recognition of a trigger signal, with flow detection at the patient wye. The sample and control cycle of the ventilator (the value of *i* in Equation 2) is frequent enough to yield essentially constant tracking of patient inspiration. At every ith interval, the software identifies instantaneous lung flow ($\dot{V}^i_L$), which is impeded by the resistances of the artificial airway and patient airways) and integrates this flow to yield an estimate of instantaneous lung volume, (V^i_L), which is impeded by the elastic recoil of the lung and thorax).

Using the values for instantaneous lung flow and lung volume, PAV+ software calculates each of the pressure elements in Equation 2, which gives the value of P_{MUS} at each ith interval.

At this point, Equation 2 and the subsequent analysis identifies that an appropriate patient, supported by PAV+ and with an active P_{MUS} (an absolute requirement) will, within a few breaths, enable the algorithm to obtain reasonable estimates of R_{PAV} and E_{PAV}. Once these physiologic data are captured (and over a relatively brief time as they are improved and stabilized), the PAV+ algorithm mirrors the patient's respiratory mechanics, which then allows the ventilator to harmoniously amplify P_{MUS}. The key point to recognize is that patient's continuous breathing effort "drives" the PAV+ support — no effort, no support.

The % Supp setting specifies the amount of resistance- and elastic-based pressure to be applied at each ith interval at the patient wye.

By taking all of the above information into consideration, EQUATION 2 can be rewritten to include the % Supp setting recognizing that $\dot{V}^i_L$ and V^i_L are driven by the patient, not by the ventilator. (It is important to note that the ventilator is not amplifying its own flow — only the flow generated by P_{MUS}.)

EQUATION 4

$$P^i_{wye} = S(\dot{V}^i_L \times R^i_{airway}) + S(\dot{V}^i_L \times K_1) + S(V^i_L \times K_2)$$

P^i_{wye}	Pressure generated by the ventilator in response to the instantaneous values of lung flow and lung volume at the wye. This value is the sum of the three individual pressure elements (in parentheses) in Equation 4	S	% Supp setting/100 (ranges from 0.05 to 0.95

Resulting Pressure Gradient

The pressure gradient driving breathing gas into the patient's lungs is given by the sum of P^{i}_{wye} and the patient's inspiratory effort, therefore:

EQUATION 5

$$\Delta P^{i}_{GRADIENT} = P^{i}_{wye} + P^{i}_{MUS}$$

$\Delta P^{i}_{GRADIENT}$	Instantaneous pressure gradient	P^{i}_{MUS}	Instantaneous pressure generating capability of patient's inspiratory muscles
p^{i}_{wye}	Pressure generated by the ventilator in response to the instantaneous values of lung flow and lung volume at the wye		

D.5.5 Protection Against Hazard

PAV+ software is designed to reduce the risk that hyperinflation may occur. The potential for hyperinflation could arise if the software were to overestimate actual patient resistance or underestimate actual patient lung-thorax compliance (that is, to overestimate actual elastance). If the software cannot generate valid estimates of R_{PAV} and C_{PAV}, PAV+ cannot start. If, after startup, the values of R_{PAV} and C_{PAV} cannot be updated with valid new values, the previous values become less reliable.

The stability of PAV+ is primarily determined by the relationship between the true lung elastance [E_L (true)] and the true lung volume [V_L(true)]. Although P^{i} wye (resistive) also plays a part, the following discussion focuses on the elastic component.

At all lung volumes, the true state of the lung and thorax is expressed by:

$$P^{i}_{L\ recoil} = V^{i}_{L\ (true)} \times E_{L\ (true)}$$

$P^{i}_{L\ recoil}$ True lung recoil pressure

$V^{i}_{L\ (true)}$ True instantaneous volume of the lung

$E_{L\ (true)}$ True lung elastance

Over-inflation will not occur as long as P^{i}_{wye} (elastic) < $P^{i}_{L\ recoil}$, which is equivalent to the inequality:

$$S[V^{i}_{L}\ (estimated) \times K_2] < V^{i}_{L}\ (true) \times E_{L}(true)$$

where:

$$K_2 = E_{PAV}{}^{1}$$

1. see equations 2 and 4

As long as E_{PAV} (estimated) = E_{PAV} (true) and V^{i}_{L} (estimated) = V^{i}_{L} (true) then $P^{i}_{recoil} > P^{i}_{wye}$ even at high values of % Supp (i.e. between 85% and 95%).

This means that if the pressure applied to the lung-thorax is never greater than E_L (true) x V_L, lung volume will collapse if wye flow vanishes. As long as E_{PAV} (estimated) ≤ E_L (true), V^{i}_{L} (estimated) ≤ V^{i}_{L} (true), and R_{PAV} (estimated) ≤ R_L(true), P_{MUS} is the modulator of P^{i}_{wye}.

Hyperinflation could occur if the estimated E_{PAV} were greater than the true value of E_L. At a high % Supp setting, P^{i}_{wye} (elastic) could exceed $P^{i}_{L\ recoil}$, causing a self-generating flow at the patient wye, which in turn would cause a self-generating inflation of the lungs. This is part of the reason that the % Supp setting is limited to 95%.

Likewise, if the estimated R_{PAV} were to exceed the true value of R_L at a high % Supp setting, P^{i}_{wye} (resistive) could exceed the value necessary to compensate for pressure dissipation across the artificial and patient airways, resulting in early hyperinflation of the lungs. As flow declines after the first third of inspiration, however, the hyperinflating effect would most likely disappear.

PAV+ software includes these strategies to minimize the possibility of hyperinflation of the lungs:

1. The maximum % Supp setting is limited to 95%.

2. The raw data for R_{PAV} and C_{PAV} are checked for graph/math logic, and estimated mechanics values are checked against PBW-based physiologic boundaries. These checks reduce the possibility of overestimating patient resistance or underestimating patient compliance, which could lead to potential over-inflation.

3. The high inspiratory tidal volume limit ($\bar{\uparrow}V_{TI}$) places an absolute limit on the integral of lung flow (including leak flow), which equals lung volume. If the value of V_{TI} reaches this limit, the ventilator truncates inspiration and immediately transitions to exhalation.

4. The $\bar{\uparrow}V_{TI}$ setting places an upper limit on the value of the $P^{VOLUME}_{PATIENT}$ component of P^{i}_{wye} (see Equations 3 and 4). At the beginning of each new inspiration, PAV+ software calculates a value for $P^{VOLUME}_{PATIENT}$ as follows:

$$P^{*}_{wye} \text{ (elastic threshold limit)} = 0.75 \times (V_{TI} \times E_{PAV})$$

where P^{*}_{wye} is the unique value for the elastic threshold limit of P^{i}_{wye} that will cause the lung volume to expand to 75% of $\bar{\uparrow}V_{TI}$. When P^{i}_{wye} (elastic) = P^{*}_{wye} (elastic threshold limit), the software stops increasing P^{i}_{wye} (elastic). This means that any further increase in lung volume must be accomplished by the patient, which tends to hasten the conclusion of inspiratory effort and avoid truncation due to lung volume reaching the $\bar{\uparrow}V_{TI}$ limit.

5. The high inspiratory pressure limit ($\bar{\uparrow}P_{PEAK}$) applies to all breaths, and is used by PAV+ software to detect the high compensation pressure condition ($\uparrow P_{COMP}$):

$$\uparrow P_{COMP} = \bar{\uparrow}P_{PEAK} - 5 \text{ cm}H_2O \text{ or } 35 \text{ cm}H_2O, \text{ whichever is less}$$

If the user-adjustable $\bar{\uparrow}P_{PEAK}$ limit is reached, the ventilator truncates inspiration and immediately transitions to exhalation. If P^{i}_{wye} (the targeted wye pressure calculated in Equation 4) equals the $\uparrow P_{COMP}$ for 500 ms, the inspiration is truncated and exhalation begins. Further, when $P^{i}_{wye} = \uparrow P_{COMP}$, P^{i}_{wye} is limited to $\uparrow P_{COMP}$.

Although this freezes the value of P^{i}_{wye}, patient activity such as coughing could drive P^{i}_{wye} to $\overline{\uparrow}P_{PEAK}$, causing inspiration to end.

The rapid rise of P^{i}_{wye} to the $\uparrow P_{COMP}$ limit would likely occur in the first third of inspiration, and only if R_{PAV} were overestimated and % Supp were set above 85%. The $\uparrow P_{COMP}$ condition guards against over-inflation due to overestimation of R_{PAV}.

6. The % Supp setting ranges from 5 to 95% in 5% increments. Reducing the level of support decreases the possibility of over-inflation. A significant decrease could produce a sensation of inadequate support, and the patient would absorb the additional work of inspiration or require an increase in the level of support.

   A significant increase could cause a surge in the ventilator generated value for P_{wye}, which in turn could cause P^{i}_{wye} to reach $\overline{\uparrow}P_{COMP}$ and lead to temporary patient-ventilator disharmony. To minimize this possibility, PAV+ software limits the actual increase in support to increments of 10% every other breath until the new setting is reached.

7. Spirometry remains active during PAV+ operation. $\overline{\uparrow}V_{TI}$ can be set high enough to allow spontaneous sigh breaths, while $\downarrow\dot{V}_{E\,TOT}$ and $\overline{\uparrow}\dot{V}_{E\,TOT}$ remain active to reveal changes in minute ventilation.

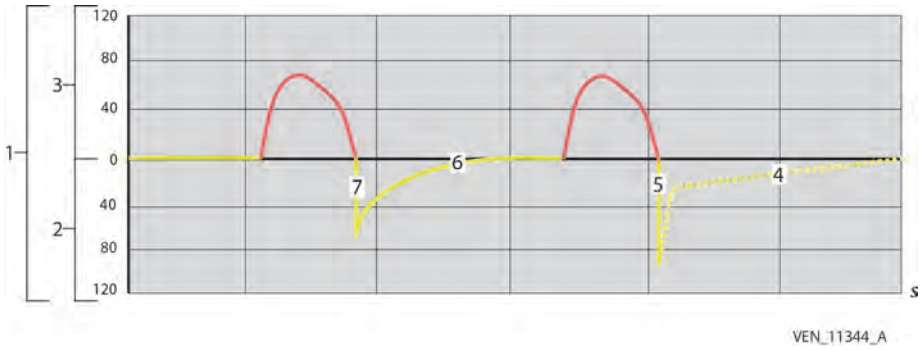
   Because PAV+ cannot operate without valid estimates of R_{PAV} and C_{PAV}, and because those values are unknown when PAV+ starts, a startup routine obtains these values during four maneuver breaths that include an end inspiratory pause that provides raw data for R_{PAV} and C_{PAV}, and both estimated values must be valid. If either value is invalid during any of the four startup breaths, the software schedules a substitute maneuver breath at the next breath. Reference *PAV+*, p. D-3.

   A low-priority alarm becomes active if a 45-second interval elapses without valid estimates for R_{PAV} and C_{PAV}. If the condition persists for 90 seconds, the alarm escalates to medium-priority. If the condition persists for 120 seconds, the alarm escalates to high priority. The $\downarrow\dot{V}_{E\,TOT}$ and$\uparrow f_{TOT}$ alarms are also associated with this condition.

   Similarly, if R_{PAV} and C_{PAV} cannot be updated with valid values after a successful PAV+ startup, a low-priority alarm is activated if the condition persists for 15 minutes. If the values still cannot be updated with valid values after 30 minutes, the alarm escalates to medium priority.

8. If PAV+ estimates a high lung resistance following a sharp spike in the expiratory flow waveform, then a PBW-based resistance value is used. Reference the waveform and table below.

Figure D-3. Use of Default Lung Resistance



1	Flow ($\dot{V}$)	5	High peak expiratory flow
2	Expiration	6	Exhalation with normal return to zero flow
3	Inspiration	7	Normal peak expiratory flow
4	Exhalation with slow, restricted return to zero flow		

Table D-4. Default PBW-based Resistance Values

PBW (kg)	Resistance ($cmH_2O/L/s$)	PBW (kg)	Resistance ($cmH_2O/L/s$)	PBW (kg)	Resistance ($cmH_2O/L/s$)	PBW (kg)	Resistance ($cmH_2O/L/s$)
25	18.1	43	13.5	61	11.3	79	10.1
26	17.7	44	13.3	62	11.2	80	10.1
27	17.4	45	13.2	63	11.1	81 to 150	10
28	17.1	46	13.0	64	11.0		
29	16.8	47	12.9	65	10.9		
30	16.5	48	12.7	66	10.9		
31	16.2	49	12.6	67	10.8		
32	15.9	50	12.4	68	10.7		
33	15.7	51	12.3	69	10.7		
34	15.4	52	12.2	70	10.6		

Table D-4. Default PBW-based Resistance Values (Continued)

PBW (kg)	Resistance ($cmH_2O/L/s$)	PBW (kg)	Resistance ($cmH_2O/L/s$)	PBW (kg)	Resistance ($cmH_2O/L/s$)	PBW (kg)	Resistance ($cmH_2O/L/s$)
35	15.2	53	12.1	71	10.5		
36	14.9	54	12.0	72	10.5		
37	14.7	55	11.8	73	10.4		
38	14.5	56	11.7	74	10.4		
39	14.3	57	11.6	75	10.3		
40	14.1	58	11.5	76	10.3		
41	13.9	59	11.4	77	10.2		
42	13.7	60	11.3	78	10.2		

E NeoMode 2.0 Appendix

E.1 Overview

This appendix describes how to use NeoMode 2.0 software on the Puritan Bennett™ 980 Neonatal Ventilator. NeoMode 2.0 enables the use of the ventilator with neonatal patients and is included with all Puritan Bennett™ 980 Neonatal Ventilators, and Puritan Bennett™ 980 Universal Ventilators. In order for a Puritan Bennett™ 980 Pediatric-Adult Ventilator to be used with Neonatal patients, the NeoMode 2.0 software option must be installed.

E.2 Intended Use

NeoMode 2.0 is intended to provide respiratory support to neonatal patients with predicted body weights as low as 0.3 kg (0.66 lb). It is intended to cover a wide variety of clinical patient conditions in hospitals and hospital-type facilities, and may be used during intra-hospital and intra-hospital-type facility transport. It supports delivered tidal volumes as low as two (2) mL.

E.3 Safety Symbol Definitions

This section contains safety information for users, who should always exercise appropriate caution while using the ventilator.

Table E-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.

E.4 Safety Information



WARNING:
The Puritan Bennett™ 980 Series Ventilator contains phthalates. When used as indicated, very limited exposure to trace amounts of phthalates may occur. There is no clear clinical evidence that this degree of exposure increases clinical risk. However, in order to minimize risk of phthalate exposure in children and nursing or pregnant women, this product should only be used as directed.



WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.



WARNING:
Neonatal patients are at risk for hypercarbia or hypoxemia during $\downarrow\dot{V}_{E\,TOT}$ alarm conditions.

WARNING:
Disabling the low exhaled minute volume ($\downarrow\dot{V}_{E\ TOT}$) alarm increases the patient's risk of Hypercarbia or Hypoxemia.

WARNING:
When Using NIV, the patient's exhaled tidal volume (V_{TE}) could differ from the ventilator's monitored patient data value for V_{TE} due to leaks around the interface. To avoid this, ensure Leak Sync is installed. When NIV is selected, Leak Sync is automatically enabled.

E.5 Description

The ventilator determines values for operational variables and allowable settings based on breathing circuit type and predicted body weight (PBW). The PBW range for neonates is 0.3 kg to 7.0 kg (0.66 lb to 15 lb). Software controls prevent inadvertent mismatching of patient size and breathing circuit type. A neonatal breathing circuit connects to a neonatal expiratory filter which must be used with the neonatal adapter door assembly.

Note:
To enable NeoMode 2.0, select the neonatal breathing circuit type in Short Self Test (SST). Breathing circuit type can only be changed during SST. NeoMode 2.0 software restricts the circuit type selection to neonatal.

E.6 Neonatal Door and Filter Installation

WARNING:
Removing the expiratory filter while the patient is connected to the ventilator can cause a loss of circuit pressure, ventilator autotriggering, or direct contact with liquid.

Caution:
Do not pull on door while expiratory filter latch is closed, as damage to the ventilator can result.

Note:
Reference the Inspiratory filter and expiratory filter instructions for use (IFU) for information on filtration efficiency and filter resistance.

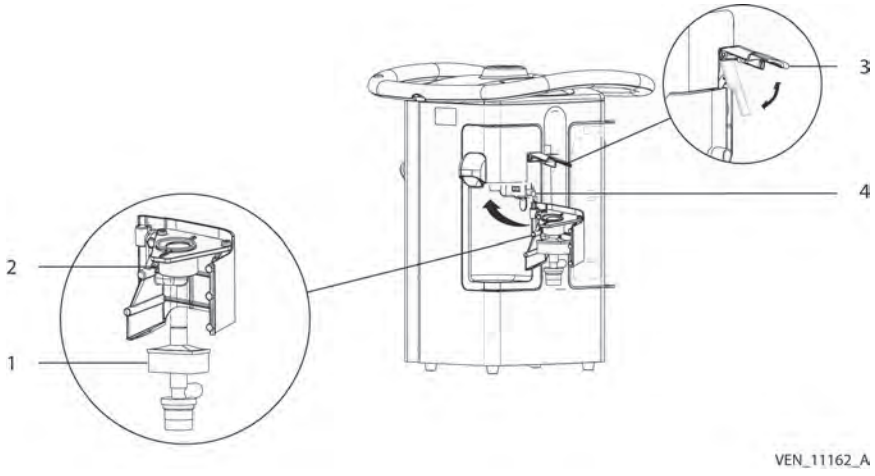
To install the neonatal adapter door

1. Remove expiratory limb of patient circuit from expiratory filter.
2. Lift expiratory filter latch. Reference *Installing Neonatal Filter and Door*, p. E-4.
3. Remove existing expiratory filter door. by lifting it off of pivot pins.
4. Fit neonatal adapter door onto pivot pins.

To install neonatal expiratory filter assembly

1. With the door still open, push the neonatal filter straight up into the adapter.
2. Close the door.
3. Lower the expiratory filter latch.
4. Re-attach expiratory limb of patient circuit to filter.

Figure E-1. Installing Neonatal Filter and Door



1	Neonatal expiratory filter	3	Expiratory filter latch
2	Neonatal adapter door	4	Filter door pivot pin

WARNING:

- **To ensure all breathing circuit connections are leak tight, perform a circuit leak test by running SST every time the filter is installed. The circuit leak test can be performed as an individual test from the SST startup screen, but after the leak test is performed, the entire suite of SST tests must be performed without a failure before ventilation can begin.**
- **Empty the condensate vial before fluid reaches the maximum fill line. Condensate vial overflow can enter the filter or the breathing circuit, and can cause increased expiratory flow resistance. Change the filter if it appears to be saturated.**
- **The neonatal expiratory filter and condensate vial is a single unit and is for single-patient use, only. Do not attempt to sterilize the filter assembly.**

WARNING:

Adding accessories to the ventilator can change the pressure gradient across the *ventilator breathing system (VBS)* and affect ventilator performance. Ensure any changes to the recommended ventilator circuit configurations do not exceed the specified values for inspiratory and expiratory pressure drop. Reference the table *Technical Specifications* on *p. 11-3* in this manual. If adding accessories to the patient circuit, always run SST to establish circuit compliance and resistance prior to ventilating the patient.

Note:

If the ventilator has not reached operating temperature from recent usage, allow it to warm up for at least 15 minutes before running SST to ensure accurate testing.

Note:

Check the inspiratory and expiratory limbs of the breathing circuit and in-line water traps regularly for water buildup. Under certain conditions, they can fill quickly. Empty and clean the in-line water traps as necessary. Reference the manufacturer's instructions for additional information.

E.7 How to Empty the Condensate Vial

The condensate vial may accumulate liquid, especially if a non-heated wire patient circuit is in use.

WARNING:
To avoid liquid entering the ventilator, empty the condensate vial before the liquid level reaches the maximum fill line.

The condensate vial assembly is integrated with the neonatal expiratory filter and does not contain a drain port. Empty the condensate vial when fluid reaches the maximum fill line.

To empty the condensate vial

1. While holding the expiratory filter, twist the condensate vial clockwise approximately one quarter turn to remove it.
2. Remove by carefully lowering the vial all the way down to the base of the exhalation compartment and then slide the vial out.
3. Quickly empty the condensate vial.
4. Replace the condensate vial by carefully sliding the vial into position, lifting it upward to the filter assembly, and turning counterclockwise until it reaches the stop.

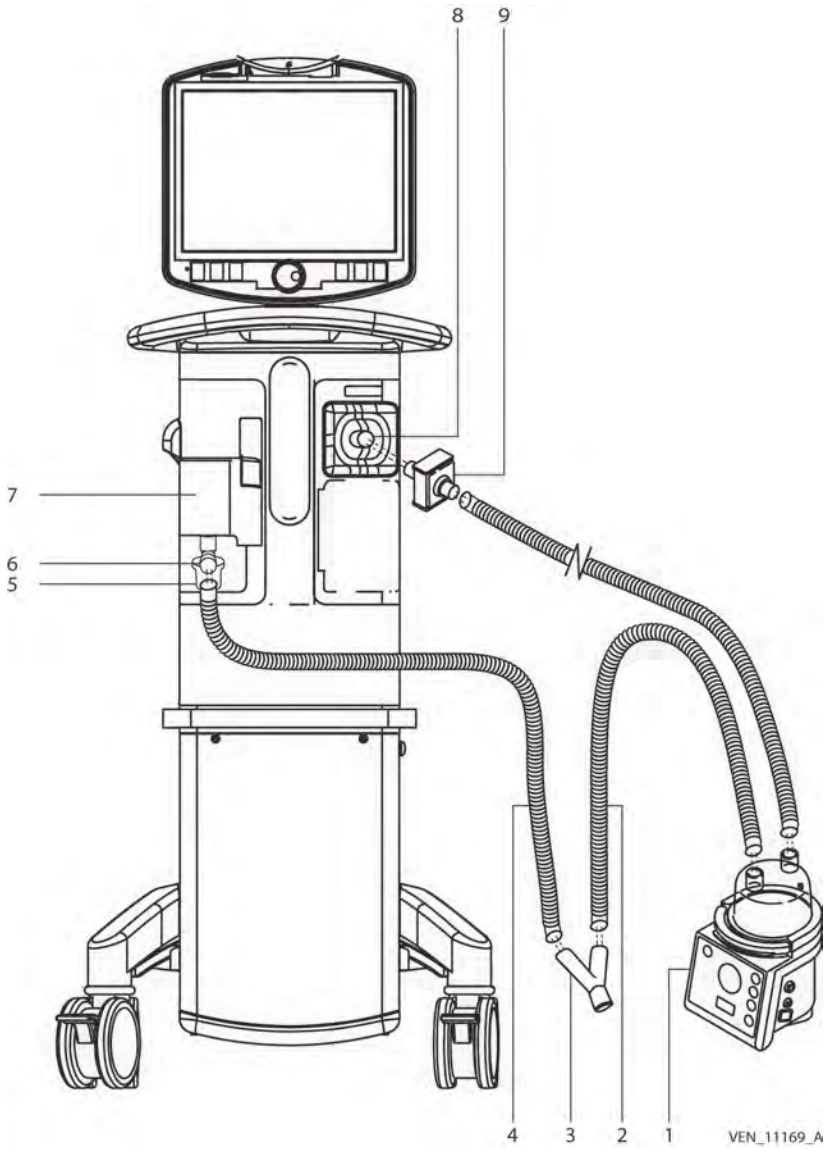
Note:
Condensate vial removal may cause the loss of system pressure and a disconnect alarm.

E.8 Connecting the Breathing Circuit

WARNING:
Use one of the ventilator breathing circuits listed, Reference *Recommended Breathing Circuits*, p. E-8 or their equivalent. This ensures that maximum pressure/flow values specified by EN794-1 are not exceeded. Using a circuit with a higher resistance does not prevent ventilation, but can cause an SST fault or compromise the patient's ability to breathe through the circuit.

Reference *How to Connect the Breathing Circuit*, p. E-7 to connect the breathing circuit.

Figure E-2. How to Connect the Breathing Circuit



1	Humidifier	6	From Patient port
2	Patient circuit inspiratory limb	7	Neonatal expiratory filter (installed in adapter door)
3	Patient circuit wye	8	To Patient port
4	Patient circuit expiratory limb	9	Inspiratory filter
5	Condensate vial		

Table E-2. Recommended Breathing Circuits

Patient Circuit	Part number
Ventilator breathing circuit, Neonatal disposable, DAR™ (not available in USA)	3078447
Ventilator breathing circuit, Neonatal, disposable, Hudson RCI/Teleflex	780-06
Ventilator breathing circuit, Neonatal, disposable, Fisher & Paykel	RT235

E.9 Ventilation Features

Ventilation using NeoMode 2.0 is performed exactly as described in *Chapter 4* of this manual. Reference *Ventilator Operation*, p. 4-7. If using a Puritan Bennett™ 980 Neonatal Ventilator, NeoMode 2.0 is already in use and a neonatal patient circuit is the only choice available when performing SST. If using a Puritan Bennett™ 980 Pediatric-Adult Ventilator or Puritan Bennett™ 980Universal Ventilator, the NeoMode 2.0 software option must be installed and SST must be run using a neonatal patient circuit.

WARNING:
Always run SST prior to patient ventilation, ensuring that all accessories used during ventilation are in the ventilator breathing system when SST is run. This ensures correct calculation of compliance and resistance. Reference *SST (Short Self Test)*, p. 3-46 for more information.

E.9.1 Predicted Body Weight (PBW) vs. Patient Length

Reference *Predicted Body Weight (PBW) Calculation* in *Chapter 4* of this manual for tables of PBW values associated with patient length in centimeters and inches, respectively.

E.9.2 Elevate O_2

In NeoMode 2.0, the elevate O_2 control works exactly as described in *Chapter 3* of this manual, except when the ventilator is in stand-by or circuit disconnect states. If the elevate O_2 function is used during these conditions,

the value chosen for elevate O_2 applies to the currently delivered oxygen concentration (which is 40% O_2 in these cases) and not the set oxygen concentration.

E.9.3 CPAP Mode

When using NeoMode 2.0 and ventilating with non-invasive ventilation (NIV), a separate CPAP mode allows spontaneous breathing with a desired PEEP level. In order to limit inadvertent alarms associated with the absence of returned volumes in nasal CPAP breathing, CPAP does not make available exhaled minute volume and exhaled tidal volume alarm settings. Since some neonates don't trigger breaths, the default apnea interval, T_A, is set to OFF. Also, some settings changes will initiate a PEEP restoration breath before phasing in those changes.

Note:
In CPAP, Apnea Time, T_A can be adjusted, if desired. It merely defaults to OFF to avoid inadvertent alarms. The message "APNEA DETECTION DISABLED" is displayed at the bottom of the GUI screen. The attention icons are also displayed.

To set the ventilator for CPAP

1. Select *New Patient* from the ventilator's startup screen or touch *Vent Setup*.
2. Touch *PBW* and turn the knob to set the PBW.
3. Select NIV as the Vent type.
4. Touch *CPAP*.
5. Touch each ventilator setting and turn the knob to select appropriate ventilator settings. When finished, touch *Accept* or *Accept ALL*.
6. Complete the setup by setting the apnea parameters and alarm limits from their respective tabs.

Figure E-3. CPAP Setup Screen



E.9.4 Entering CPAP From Other Ventilation Modes

Entering CPAP mode from other ventilation modes or vent types requires using the NIV Vent type.The section, *Non-invasive Ventilation (NIV)* in *Chapter 4* of this manual explains how the ventilator transitions from INVASIVE TO NIV vent type.

To enter CPAP mode for an existing patient



1. Touch *Vent Setup* at the lower left of the GUI screen.
2. Touch *NIV* Vent type. CPAP is only allowed during NIV.
3. Touch *CPAP*. The ventilator enters CPAP mode.
4. Set an apnea interval, T_A, if appropriate, as it defaults to OFF in CPAP.

Note:
Exhaled minute volume ($\dot{V}_{E\ TOT}$), exhaled tidal volume ($V_{TE\ SPONT}$), and inspired tidal volume (V_{TI}) alarms are disabled upon entry into CPAP.

E.9.5 Exiting CPAP Mode

When changing the mode from CPAP to any other mode, several transition rules take effect:

- The $\dot{V}_{E\ TOT}$, $V_{TE\ MAND}$, $V_{TE\ SPONT}$, and V_{TI} alarms are set to their respective new patient defaults.
- When transitioning from apnea interval set to OFF to an apnea interval of time (T_A), the new setting is phased in immediately.
- The $\dot{V}_{E\ TOT}$, $V_{TE\ MAND}$, $V_{TE\ SPONT}$, and V_{TI} alarm sliders appear in the alarm settings screen according to their applicability to the selected mode.

E.9.6 Compliance Compensation

Reference *Compliance Compensation in Volume-based Breaths* in *Chapter 10* of this manual for a complete discussion of compliance compensation. Compliance compensation in NeoMode 2.0 is implemented exactly as described in the aforementioned reference.

Note:
If the patient's compliance decreases beyond the limits of compliance compensation, the ventilator relies on the $\uparrow P_{PEAK}$ alarm setting to truncate the breath and switch to exhalation.

E.9.7 Settings, Alarms, and Monitored Patient Data

WARNING:
Monitor the patient closely if alarms are disabled: there are no audible or visual annunciations for out-of-range conditions when volume, pressure, or apnea alarms are disabled (turned OFF).

Reference the tables for Ventilator Settings, Alarm Settings, and Patient Data in *Chapter 11* of this manual for the ranges for each ventilator setting or data value. Most settings, however, are also limited by other settings or conditions (for example, a low alarm limit is always limited by the corresponding high alarm limit). Review the prompt area when making settings changes.

Volume Accuracy

Volume accuracy testing in VC+ was conducted to demonstrate performance of delivered and monitored parameters. The following tables provide a summary of the actual results obtained within the range of two (2) mL to 25 mL collected during test execution.

The first column (Set Tidal Volume) represents the desired volume setting in milliliters (mL). The second column represents the total number of test points for test cases executed at that specific setting. The third column is the mean (Mean Value) of the ventilators and test cases executed for the setting listed. The fourth column represents the standard deviation of measurements taken for the ventilators and test cases executed at the setting listed.

The measurements were taken using instrumentation located at the patient-connection port. Accessories such as filters and humidifiers were in the circuit during the test. Values were BTPS and compliance compensated. A sample size of five (5) ventilators was used to conduct the testing. Testing was conducted at 22°C ± 5°C.

Table E-3. Delivered Volume Accuracy

Set Tidal Volume (mL)	Number of Test Points	Mean Value	STD
2	150	2.067	0.198
5	270	4.853	0.324
15	240	15.108	0.383
25	270	24.608	0.607

Table E-4. Monitored Inspired Volume (V_{TI}) Accuracy

Set Tidal Volume (mL)	Number of Test Points	Mean Value	STD
2	150	2.055	0.192
5	270	4.872	0.346
15	240	15.235	0.379
25	265	24.633	0.566

Table E-5. Monitored Exhaled Tidal Volume (V_{TE}) Accuracy

Set Tidal Volume (mL)	Number of Test Points	Mean Value	STD
2	150	2.212	0.274
5	270	5.892	0.607
15	240	16.145	0.851
25	265	25.492	0.819

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F Proximal Flow Option Appendix

F.1 Overview

This appendix describes the operation of the Proximal Flow Option for the Puritan Bennett™ 980 Series Ventilator. The Proximal Flow Option is solely used for monitoring flows, pressures, and tidal volumes and does not control these parameters in any way.

The Proximal Flow Sensor is designed to measure the lower flows, pressures and tidal volumes at the patient wye typically associated with invasively ventilated neonatal patients.

For general parameter and general ventilator setup information, reference *Chapter 4* in this manual.

F.2 Intended Use

The Proximal Flow Option is used for measuring flows, pressures, and tidal volumes of invasively ventilated neonatal patients with predicted body weights (PBW) of 0.3 kg (0.66 lb) to 7.0 kg (15.4 lb) using ET tube sizes from 2.5 mm to 4.0 mm. The NeoMode 2.0 software option must also be installed on the ventilator.

F.3 Safety Symbol Definitions

This section contains safety information for users who should always exercise appropriate caution while using the ventilator.

Table F-1. Safety Symbol Definitions

Symbol	Definition
	**WARNING** **Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.**
	**Caution** **Cautions alert users to exercise appropriate care for safe and effective use of the product.**
	**Note** Notes provide additional guidelines or information.

F.4 Software/Hardware Requirements

The Proximal Flow Option requires installation of the NeoMode 2.0 software option or a Puritan Bennett™ 980 Neonatal Ventilator must be used. Details regarding NeoMode 2.0 can be found in the *NeoMode 2.0 Appendix* .

F.5 Safety Information



WARNING:
The Puritan Bennett™ 980 Series Ventilator contains phthalates. When used as indicated, very limited exposure to trace amounts of phthalates may occur. There is no clear clinical evidence that this degree of exposure increases clinical risk. However, in order to minimize risk of phthalate exposure in children and nursing or pregnant women, this product should only be used as directed.



WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings to use for that patient based on clinical judgment, the condition and needs of the patient, and the benefits, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not those are best for the patient's current needs.

WARNING:
Inspect the Proximal Flow Sensor prior to use, and do not use it if the sensor body, tubing, or connector are damaged, occluded, or broken.

WARNING:
Do not use the Proximal Flow Sensor if there are kinks in the tubing.

WARNING:
Prior to patient ventilation with the Proximal Flow Option, run SST with the exact configuration that will be used on the patient. This includes a neonatal patient circuit, Proximal Flow Sensor, and all accessories used with the patient circuit. If SST fails any Proximal Flow Sensor test, check the patient circuit and the Proximal Flow sensor for leaks or occlusions and replace the flow sensor, if necessary. If SST continues to fail, it may indicate a malfunction or a leak within the Proximal Flow hardware which could compromise accuracy or increase the likelihood of cross-contamination; thus, replace the Proximal Flow hardware.

WARNING:
Changing ventilator accessories can change the system resistance and compliance. Do not add or remove accessories after running SST.

WARNING:
If the Proximal Flow Option fails to respond as described in this appendix, discontinue use until correct operation is verified by qualified personnel.

WARNING:
The Proximal Flow Sensor measures gas flow at the patient wye. The actual volume of gas delivered to the patient may be affected by system leaks between the patient and the Proximal Flow Sensor, such as a leak that could occur from the use of an uncuffed endotracheal tube.

WARNING:
Position the Proximal Flow Sensor exactly as described in this appendix or the Instructions for Use (IFU) provided with the sensor.

WARNING:
Do not position the Proximal Flow Sensor cables or tubing in any manner that may cause entanglement, strangulation or extubation which could lead to hypercarbia or hypoxemia. Use the cable management clips supplied to mitigate this risk.

WARNING:
To reduce the risk of extubation or disconnection, do not apply tension to or rotate the Proximal Flow Sensor by pulling on the Proximal Flow Sensor's tubing.

WARNING:
Do not install the Proximal Flow Sensor in the patient circuit if the sensor is not also connected to the BDU.

WARNING:
Excessive moisture in the Proximal Flow Sensor tubing may affect the accuracy of the measurements. Periodically check the sensor and tubing for excessive moisture or secretion build-up.

WARNING:
The Proximal Flow Sensor is intended for single use only. Do not re-use the sensor. Attempts to clean or sterilize the sensor may result in bioincompatibility, infection, or product failure risks to the patient.

WARNING:
Install the Proximal Flow Sensor as shown. Reference *Attaching Proximal Flow Sensor*, p. F-14. Improper orientation of the flow sensor could lead to misinterpretation of data or incorrect ventilator settings.

Caution:
Do not use aerosolized medications with the Proximal Flow Sensor. Such medications may damage the sensor.

Caution:
To prevent damage to pneumatic lines, use supplied cable management clips.

Caution:
Use only Covidien-branded Proximal Flow Sensors with the Proximal Flow Option.

F.6 Proximal Flow Option Description

The Proximal Flow Option measures pressure, flow, and volume at the patient wye. A Printed Circuit Board Assembly (PCBA) containing the electronics and pneumatics for the Proximal Flow Option is installed in the ventilator on the Option Host Card. Data measured by the Proximal Flow Sensor are displayed on the GUI for monitoring purposes, not for ventilator control. When the ventilator has a Proximal Flow Sensor installed, both proximal flow and proximal pressure measurements are obtained and displayed on the GUI.

A manual purge control is also provided to clear pneumatic lines for accurate pressure measurements. When a manual purge is requested, the ventilator will not allow another purge for at least 30 seconds. Reference *Sensor Calibration and Sensor Line Purging*, p. F-8 for more information on the purge function.

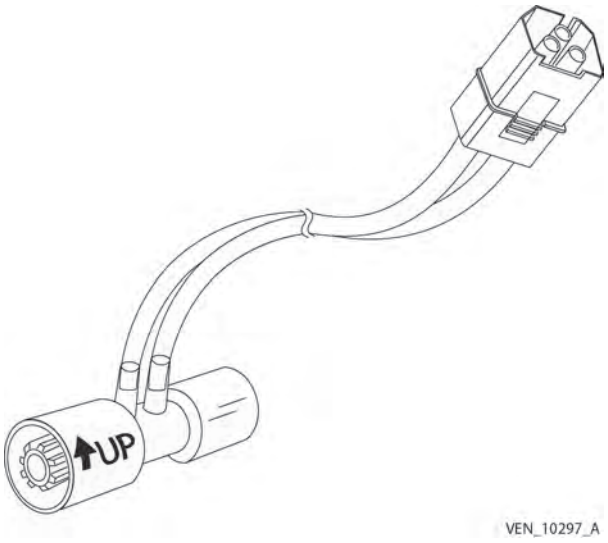
F.6.1 Proximal Flow Option components

The Proximal Flow Option consists of the following components:

Proximal Flow Option PCBA — Installed on the Option Host Card in the BDU, this printed circuit board assembly contains a pressure sensor to measure the pressure difference between the flow sensor lines and the interfaces required to convert analog measurements from the Proximal Flow Sensor into digital data displayed by the ventilator. The PCBA also contains valves and an accumulator for purging the sensor lines from blockages.

Proximal Flow Sensor — The Puritan Bennett Proximal Flow Sensor is required for use with the Proximal Flow Option. The sensor is installed near the patient circuit wye. The other end of the sensor connects to the ventilator's front panel behind a clear door designed to protect the connection point from exposure to spills or from sprayed liquids during cleaning and disinfection.

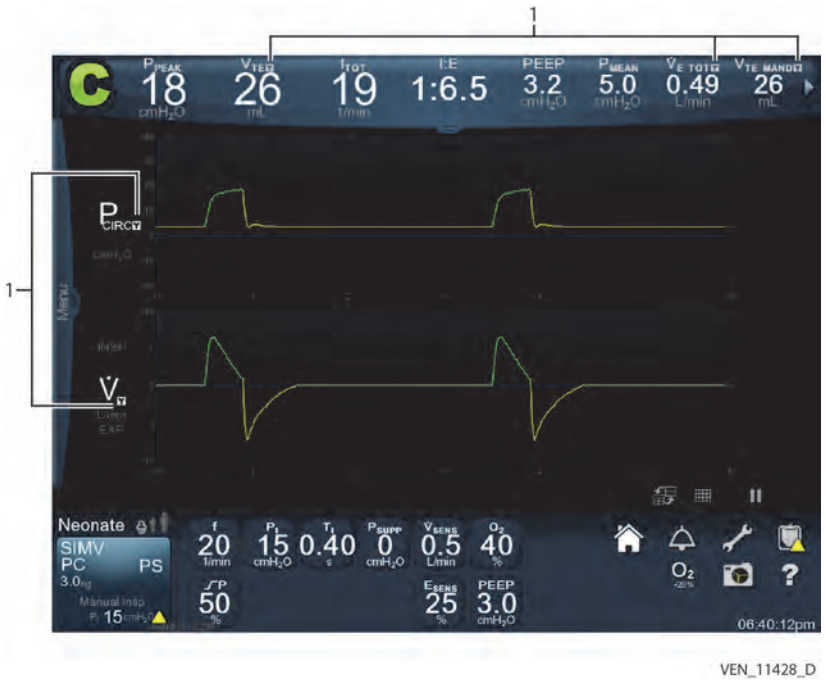
Figure F-1. Proximal Flow Sensor



F.7 On-screen symbols

When using the Proximal Flow Option, flow, pressure, and volume waveform data, along with delivered and exhaled volumes are derived from Proximal Flow Sensor measurements at the patient circuit wye. Proximal flow data are displayed on the waveform plot with a **Y** appearing in inverse video next to the measurement symbol.

Figure F-2. Sample GUI screen Showing Proximal Flow Data



1 Data measured using Proximal Flow Sensor
$\dot{V}_Y$ – Flow throughout the breath cycle (at patient circuit wye)
P_{CIRCY} – Pressure throughout the breath cycle (at patient circuit wye)

Inspired and exhaled flows and volumes at the patient wye are measured and identified by the symbols shown below, and correspond to their non-proximal flow equivalents. These values appear in the patient data panel if so configured. Reference *Vital Patient Data* on *page 3-42*, and the figure above.

Table F-2. Proximal Flow Option Patient Data Symbols

Data Symbol	Description
V_{TIY}	Inspired tidal volume (mandatory or spontaneous at patient circuit wye)
V_{TEY}	Exhaled tidal volume (at patient circuit wye)
$V_{TE\ SPONTY}$	Exhaled spontaneous tidal volume (at patient circuit wye)
$V_{TE\ MANDY}$	Exhaled mandatory tidal volume (at patient circuit wye)
$\dot{V}_{E\ TOTY}$	Exhaled total minute volume (at patient circuit wye)
$\dot{V}_{Y}$	Flow throughout the breath cycle (at patient circuit wye)
V_{TLY}	Inspired tidal volume (at patient circuit wye with Leak Sync enabled)

Note:
In the patient data symbols shown above, the "Y" appears in inverse video, as shown. Reference *Sample GUI screen Showing Proximal Flow Data*, p. F-7.

Note:
When the Proximal Flow and Leak Sync options are enabled, the following parameters are available for display:

- V_{TLY} and V_{TL}
- LEAK and $LEAK_Y$

When only the Proximal Flow option is enabled, V_{TIY} and V_{TI} are available for display

When a "Y" appears in the symbol, the data are measured with the proximal flow sensor. When a "Y" is absent from the symbol, the data are measured by the ventilator's internal flow sensors.

F.8 Sensor Calibration and Sensor Line Purging

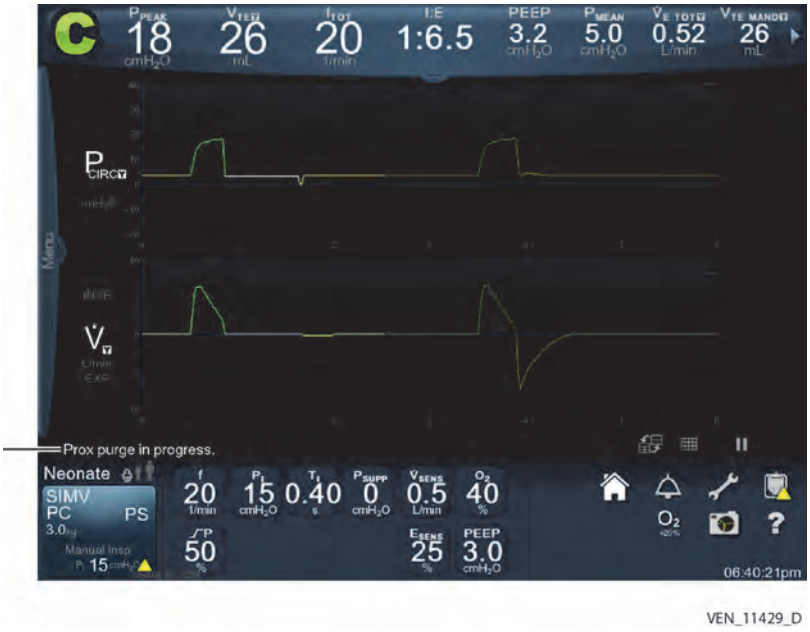
To ensure accurate pressure and flow measurements, the ventilator performs an autozero function to calibrate the Proximal Flow Sensor. It does this by periodically opening the pressure sensor on the Proximal Flow Option PCBA to atmosphere during exhalation, and uses the resulting measurements as offset corrections.

The purge function is designed to clear the pneumatic lines of fluids that may collect, and is performed periodically by sending a brief flow of air through the sensor lines. Autozero and purge functions are only active during exhalation which limits the effect of the purge gas on delivered oxygen concentration.

During the autozero or automatic purge processes, the measurement and display of proximal flow data is not shown in real time and a brief message appears on the GUI indicating the purge process is occurring.

During autozero or automatic purge processes, the pressure waveforms, when shown display the current PEEP value and the flow waveform, when shown, displays a value of 0.

Figure F-3. Message During Autozero and Purge Processes



F.9 SST Requirements

SST must be run prior to ventilation and all circuit components and accessories must be installed in the configuration to be used on the patient in order for the ventilator to calculate the correct compliance and resistance. This includes a neonatal patient circuit, Proximal Flow Sensor, and other accessories used during ventilation. Reference *To run SST* in *Chapter 3* of this manual. There is also a table listing the general SST test sequence located in that section. Ref-

erence the table below for a listing of the test sequence when running SST with the Proximal Flow Option.

Note:
Failure of the Proximal Flow Option to pass SST does not prevent ventilation, but will prevent measurement with the Proximal Flow Option. The ventilator will use its internal flow sensors for measurement instead of the Proximal Flow Option.

Table F-3. Proximal Flow Option SST test Sequence

Test Step	Function	Comments
SST Flow Sensor Cross Check	Tests O_2 and Air Flow Sensors	N/A
SST EV Performance	Calibrates the exhalation valve and creates a table for use during calculations.	N/A
SST Circuit Pressure	Exercises delivery PSOL. Checks inspiratory and expiratory autozero solenoids. Cross-checks inspiratory and expiratory pressure transducers at various pressures.	N/A
SST Leak	Tests ventilator breathing system for leaks.	N/A
SST Exhalation Filter	Checks for exhalation filter occlusion and exhalation compartment occlusion.	Ventilator prompts the user to block the proximal flow sensor outlet during Leak test. When prompted to reconnect the patient to the expiratory filter during the Exhalation Filter test, resume blocking the proximal flow sensor outlet.
SST Circuit Resistance	Checks for inspiratory and expiratory limb occlusions, and calculates and stores the inspiratory and expiratory limb resistance parameters.	N/A
SST Circuit Compliance	Calculates the attached patient circuit compliance.	N/A
SST Prox	Verifies functionality of Proximal Flow System.	Includes tests of barometric pressure, autozero, purge, and pressure cross check functions

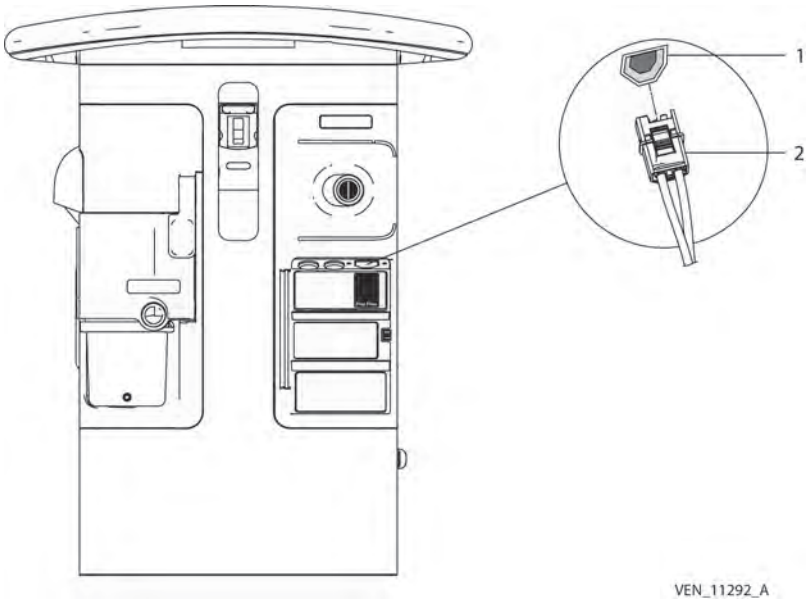
F.9.1 Attaching the Proximal Flow Sensor for SST

During SST the ventilator prompts to attach the Proximal Flow Sensor.

To attach the Proximal Flow Sensor to the patient circuit

1. Verify the Proximal Flow Sensor, pneumatic lines, and connector are not damaged.
2. Open the connector panel door and firmly attach the sensor connector to the receptacle in the BDU's front connector port labeled Prox.

Figure F-4. Attaching Proximal Flow Sensor to Ventilator



1	Proximal Flow Sensor connector insertion port	2	Proximal Flow Sensor connector

3. When prompted, block the breathing circuit wye.
4. When prompted to attach the Proximal Flow Sensor, unblock the circuit wye and insert the smaller end of the sensor into the wye.
5. When prompted, cap or seal the larger end of the sensor (marked with "UP" and an arrow).
6. Follow the prompts to complete SST.

If SST fails, check the patient circuit and flow sensor connections for leaks or occlusions and replace the Proximal Flow Sensor, if necessary. Replace the Proximal Flow Option hardware if SST continues to fail, then repeat SST to determine circuit compliance and resistance. Reference the *Puritan Bennett™ 980 Series Ventilator Hardware Options Installation Instructions*, p/n 10084704 for instructions on replacing the Proximal Flow Option hardware.

F.10 Disabling/Enabling the Proximal Flow Option

The Proximal Flow Sensor can function in the ENABLED state only if the circuit type is NEONATAL. Assuming the Proximal Flow Option is available and the vent type is INVASIVE, the New Patient default value is ENABLED. If the vent type is NON-INVASIVE, the Proximal Flow Option is DISABLED. The system becomes ENABLED again if the vent type is changed to INVASIVE.

After SST has been performed, the clinician may disable the Proximal Flow Option, if desired.

To disable or enable the Proximal Flow Option



1. In the constant access icons area, touch the configure icon. A menu containing tabs appears.
2. Touch the Options tab. A screen appears containing the Installed Options and Prox tabs.
3. Touch *Enabled* or *Disabled* to enable or disable the Prox Flow option.

Figure F-5. Enabling/disabling Proximal Flow Sensor



Note:
If the Proximal Flow Option has been disabled or enabled, SST does not have to be re-run unless the breathing circuit or other breathing system accessories have been changed, removed, or added.

F.11 Using the Proximal Flow Sensor

Review and follow all warnings prior to patient ventilation with the Proximal Flow Sensor. Reference *Safety Information*, p. F-2, and ensure the Proximal Flow Sensor option is enabled.

To connect the Proximal Flow Sensor to the ventilator

1. Verify the Proximal Flow Sensor, pneumatic lines, and connector are not damaged in any way.

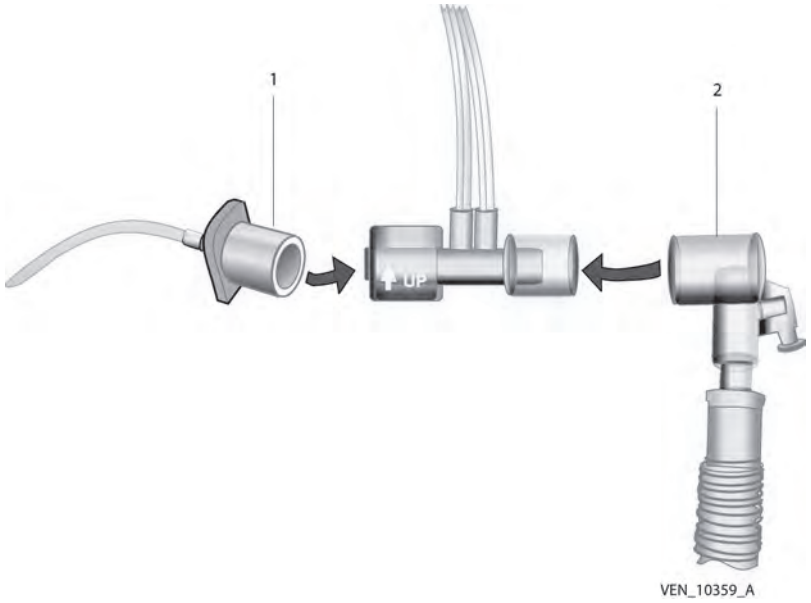
2. Open the connector panel door and firmly attach the sensor connector to the right-most receptacle in the BDU's front connector port labeled Prox. Reference *Attaching Proximal Flow Sensor to Ventilator*, p. F-11.

To attach the Proximal flow sensor between the endotracheal tube and patient circuit

1. Connect the larger end of the sensor (marked with "UP" and an arrow) to the endotracheal tube. Reference the figure below. Do not force the connection; when the sensor is oriented correctly, insertion requires little effort.

Note:
If using a Heat-Moisture Exchanger (HME) on the endotracheal tube, place the Proximal Flow Sensor between the HME and the breathing circuit wye.

Figure F-6. Attaching Proximal Flow Sensor



1	Endotracheal tube	2	Breathing circuit wye

2. Connect the smaller end of the sensor to the breathing circuit wye.

3. Ensure the sensor tubing is positioned in an upward direction, as shown in the figure above. If the sensor needs repositioning, **DO NOT** rotate it by pulling on the tubing. Reposition as follows:

   a. Grasp the sensor's plastic body with one hand and the breathing circuit wye with the other hand.

   b. Rotate the sensor body and wye towards each other until the sensor tubing is upright.

   c. Confirm a tight connection between the sensor and breathing circuit wye.

4. Use the three cable management clips provided with the sensor to attach the sensor tubing to the breathing circuit tubing. Space the clips evenly along the length of the sensor tubing. Twist the ends of each clip to close.

Note:
When the ventilator is set up for Proximal Flow Option operation, the Proximal Flow Sensor can be switched as necessary. There is no need to run SST after switching sensors unless the breathing circuit or other ventilator accessories have been changed.

F.11.1 How to Perform a Manual Purge

A manual purge may be performed any time the sensor lines contain excessive condensation, moisture, or secretions.

To perform a manual purge

1. Touch the *Configure* icon on the in the constant access icons area of the GUI.
2. Touch the Options tab. A screen appears containing the Installed Options and Prox tabs.
3. Touch the Prox tab. The Prox Setup screen appears.
4. Touch *Start* that appears next to the text "Prox Manual Purge: To begin touch the Start button". During the purge, a message appears in the GUI prompt area stating the purge process is being performed.Reference *Message During Autozero and Purge Processes*, p. F-9.

Figure F-7. Manual Purge



F.12 Alarms

If the Proximal Flow Option becomes inoperable during ventilation, the ventilator annunciates an alarm and flow sensing reverts to the ventilator's internal delivery and exhalation valve flow sensors. This switch over may be triggered by any of the following events:

- The Proximal Flow Sensor is not detected
- Pressure and flow readings are out of range
- Hardware problems are reported by the Proximal Flow Option PCBA
- There is a communication failure between the ventilator and the Proximal Flow option

If any of these conditions occur, the GUI displays an alarm message similar the one shown below.Follow the information contained in the remedy message to troubleshoot the alarm.

Figure F-8. Alarm Message — Prox Inoperative


Data from proximal flow sensor is not being used.
Check proximal flow sensor connections and tubes for occlusions or leaks.
Go to System Diag. Log
Prox Inoperative
Neonate
SIMV PC PS
06:41:32pm
VEN_11431_D

F.13 Ranges, Resolutions, and Accuracies

Reference *Patient Data Range and Resolution* in *Chapter 11* of this manual for Proximal exhaled tidal volume, Proximal inspired tidal volume, Proximal exhaled minute volume, and Proximal flow patient data parameters.

F.13.1 Proximal Flow Sensor Specifications

Table F-4. Proximal Flow Sensor Volume Accuracy

Measurement	Accuracy[1]
Exhaled tidal volume	± (1.0 mL + 10% of reading)
Inspired tidal volume	± (1.0 mL + 10% of reading)

1. The conditions under which the accuracy values apply are as follows:
   Sensor is used as described in this appendix and/or the Instructions for Use provided with the sensor

Table F-5. Proximal Flow Sensor Specifications

Parameter	Specification
Weight	6.6 g
Dead space	< 1 mL
Pressure drop	1.5 cmH_2O at 10 L/min

F.14 Part Numbers

The table below lists the part numbers for the Proximal Flow Option Kit and individual components.

Table F-6. Proximal Flow Option Component Part Numbers

Item	Part Number
Proximal Flow Option Kit Includes: Installation hardware and accessories	10084331
Proximal Flow Sensor, Neonatal (package of 10) **NOTE**: Includes 3 cable management clips	10047078
Proximal Flow Sensor module	10087622
Interconnect PCBA	10083941
Purge Control Cable	10083940
Purge Supply Line	10083966
PCBA Mounting Screws	10083963
Proximal Flow Option Label	10005748

Glossary

Table Glossary-1. Glossary of Ventilation Terms

analysis message	A message displayed on the GUI screen during an alarm condition, identifying the root cause of the alarm.
assist breath	A mandatory breath triggered by patient inspiratory effort in A/C and SIMV modes.
assist-control A/C mode	A ventilation mode where only mandatory VC, PC, or VC+ breaths are delivered to the patient.
augmented alarm	The initial cause of an alarm has precipitated one or more related alarms. When an alarm occurs, any subsequent alarm related to the cause of this initial alarm "augments" the initial alarm.
autotriggering	The ventilator delivers repeated, unintended breaths triggered by fluctuating flows or pressures as opposed to patient demand. Patient circuit leaks and low flow or pressure sensitivity settings are common causes of autotriggering.
background checks	Continuously running tests during ventilation that assess the ventilator's electronics and pneumatics hardware.
backup ventilation (BUV)	A safety net feature which is invoked if a system fault in the mix subsystem, inspiratory subsystem, or expiratory subsystem occurs compromising the ventilator's ability to ventilate the patient as set.
base flow	A constant flow of gas through the patient circuit during the latter part of exhalation during flow triggering ($\dot{V}_{-TRIG}$). The value of this base flow is 1.5 L/min greater than the operator selected value for flow sensitivity.
base message	A message given by the ventilator during an alarm condition, identifying the alarm.
batch changes	Changes to multiple settings that go into effect at the same time.
battery back-up system	The system for supplying battery back-up power to a device. The ventilator's battery back-up system consists of a single primary battery to provide up to one (1) hour of battery power to the ventilator. An optional extended battery with the same characteristics as the primary battery is available.
BD, BDU	Breath delivery or breath delivery unit. The ventilator component that includes inspiratory and expiratory pneumatics and electronics.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

BiLevel mode	A mixed ventilation mode combining mandatory and spontaneous breaths, where two levels of pressure are delivered (P_L and P_H) corresponding to expiratory and inspiratory times T_L and T_H.
BOC	British Oxygen Company. A standard for high pressure gas inlet fittings.
breath stacking	The delivery of a second inspiration before the previous exhalation is complete.
BTPS	Body temperature and pressure, saturated, 37°C, at ambient barometric pressure, at 100% relative humidity.
cmH_2O	Centimeters of water. A unit of pressure approximately equal to 1 hPa.
compliance volume	The volume of gas that remains in the patient circuit and does not enter the patient's respiratory system.
constant during rate change	One of three breath timing variables (inspiratory time, I:E ratio, or expiratory time) the operator can hold constant when the respiratory rate setting changes. Applies only to the pressure control (PC) mandatory breath type (including VC+ and BiLevel).
control breath	A ventilator-initiated mandatory breath delivered in A/C mode
CPU	Central processing unit. The electronic components of the ventilator (BD and GUI) responsible for interpreting and executing instructions entered by the operator.
dependent alarm	An alarm that arises as a result of another primary alarm (also referred to as an augmentation).
D_{SENS}	Disconnect sensitivity. A setting that specifies the allowable loss (percentage) of delivered tidal volume, which if equaled or exceeded, causes the ventilator to declare a DISCONNECT alarm. The greater the setting, the more returned volume must be lost before DISCONNECT is detected. If the Leak Sync option is in use, D_{SENS} is the maximum allowable leak rate and is expressed in terms of L/min.
DISS	Diameter index safety standard. A standard for high pressure gas inlet fittings.
E_{SENS}	Expiratory sensitivity. A setting that determines the percent of peak inspiratory flow (or flow rate expressed in L/min in a PAV breath) at which the ventilator cycles from inspiration to exhalation for spontaneous breaths. Low settings will result in longer spontaneous inspirations. In an IE Sync triggered breath, when the P_{SYNC} signal drops below the E_{SENS} setting, the ventilator cycles to exhalation.
EST	Extended self test. A comprehensive test of ventilator function, intended to be run by qualified service personnel.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

expiratory pause	an operator-initiated maneuver that closes the inspiration (proportional solenoid) and exhalation valves during the exhalation phase of a mandatory breath. The maneuver can be used to determine intrinsic (auto) PEEP ($PEEP_I$).
exhalation valve (EV)	The valve in the expiratory limb of the ventilator breathing system that controls PEEP.
f, f_{TOT}	Respiratory rate, as a setting (*f*) in A/C, SIMV, and BiLevel the minimum number of mandatory breaths the patient receives per minute. As a monitored value (f_{TOT}), the average total number of breaths delivered to the patient.
FAILURE	A category of condition detected during SST or EST that causes the ventilator to enter the safety valve open state. A ventilator experiencing a FAILURE requires removal from clinical use and immediate service.
flow pattern	A setting that determines the gas flow pattern of mandatory volume-controlled breaths.
gold standard test circuit	Test circuit designed for use with EST.
GUI	Graphical user interface. The ventilator's touch screen used to enter patient settings. and alarm settings, including off-screen keys, soft keys, and knobs.
hard bound	A ventilator setting that has reached its minimum or maximum limit.
high-priority alarm	As defined by international standards organizations, an alarm that requires immediate attention to ensure patient safety. When a high-priority alarm is active, the red high-priority LED indicator flashes and the high-priority audible alarm sounds (a repeating sequence of five tones that repeats twice, pauses, then repeats again), and the alarm banner on the GUI screen shows an alarm message with the (!!!) symbol.
HME	Heat-moisture exchanger. A humidification device, also called an artificial nose.
hPa	Hectopascal. A unit of pressure, approximately equal to 1 cmH_2O.
humidification type	A setting for the type of humidification system (HME, non-heated expiratory tube, or heated expiratory tubing) in use on the ventilator.
I:E ratio	The ratio of inspiratory time to expiratory time. Also, the operator- set timing variable that applies to PC and VC+ mandatory breaths.
inspiratory pause	An operator-initiated maneuver that closes the inspiration (proportional solenoid) and exhalation valves at the end of the inspiratory phase of a mandatory breath. The maneuver can be used to determine static compliance (C_{STAT}) and static resistance (R_{STAT}).

Table Glossary-1. Glossary of Ventilation Terms (Continued)

invasive ventilation	Patient ventilation while intubated with an endotracheal (or tracheostomy) tube.
kPa	Kilopascal. A unit of pressure approximately equal to 10 cmH_2O.
latched alarm	An alarm whose visual alarm indicator remains illuminated after the alarm has autoreset.
L/min	Liters per minute. A unit of flow.
low-priority alarm	As defined by international standards organizations, an alarm that indicates a change in the patient-ventilator system. During a low-priority alarm, the yellow low-priority LED indicator lights, the low-priority audible alarm (one tone) sounds, and the GUI screen shows an alarm banner with the (!) symbol.
lockable alarm	An alarm that does not terminate an active alarm silence function.
maintenance	All actions necessary to keep equipment in, or restore it to, serviceable condition. Includes cleaning, servicing, repair, modification, overhaul, inspection, and performance verification.
mandatory breath	A breath whose settings and timing are preset; can be triggered by the ventilator, patient, or operator.
mandatory type	The type of mandatory breath: volume control (VC), VC+, or pressure control (PC).
manual inspiration	An operator-initiated mandatory (OIM) breath.
medium-priority alarm	As defined by international standards organizations, an abnormal condition that requires prompt attention to ensure the safety of the patient. When a medium-priority alarm is active, the yellow medium-priority LED indicator flashes, the medium- priority audible alarm (a repeating sequence of three tones) sounds, and the GUI screen shows an alarm banner with the (!!) symbol.
mode	Ventilatory mode. The algorithm that determines type and sequence of breath delivery.
NIST	Non-interchangeable screw thread. A standard for high pressure gas inlet fittings.
non-invasive ventilation (NIV)	Patient ventilation without the use of an endotracheal tube; instead using interfaces such as masks, nasal prongs, or uncuffed endotracheal tubes.
non-technical alarm	An alarm caused due to a fault in the patient-ventilator interaction or a fault in the electrical or gas supplies that the practitioner may be able to alleviate.
normal ventilation	The state of the ventilator when breathing is in progress and no alarms are active.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

O_2%	Both a ventilator setting and a monitored variable. The O_2% setting determines the percentage of oxygen in the delivered gas. The O_2% monitored data is the percentage of oxygen in the gas delivered to the patient, measured at the ventilator outlet upstream of the inspiratory filter.
OIM	Operator-initiated mandatory breath. A breath delivered when the operator presses the MANUAL INSP key.
ongoing background checks	Continuously running tests during ventilation that assess the ventilator's electronics and pneumatics hardware.
OSC	Occlusion status cycling. A state invoked during a severe occlusion. In this mode, the ventilator periodically attempts to deliver a pressure-based breath while monitoring the inspiration and expiration phases for the continuing existence of the occlusion.
OVERRIDDEN	The final status of an SST or EST run in which the operator used the override feature. (The ventilator must have ended the test with an ALERT condition.) Failures cannot be overridden.
patient circuit	The entire inspiratory-expiratory conduit, including tubing, humidifier, and water traps.
patient data alarm	An alarm condition associated with an abnormal condition of the patient's respiratory status.
patient problems	A definition used by the ventilator's safety net. Patient problems are declared when patient data are measured equal to or outside of alarm thresholds and are usually self-correcting or can be corrected by a practitioner. The alarm monitoring system detects and announces patient problems. Patient problems do not compromise the ventilator's performance.
PBW	Predicted body weight, a ventilator setting that specifies the patient's body weight assuming normal fat and fluid levels. Determines absolute limits on tidal volume and peak flow, and allows appropriate matching of ventilator settings to the patient.
PC	Pressure control. A mandatory breath type in which the ventilator delivers an operator-set inspiratory pressure for an operator- set inspiratory time. Available in A/C and SIMV modes, and for operator-initiated mandatory (OIM) breaths in SPONT mode.
PE	Expiratory pressure transducer.
PEEP	Positive end expiratory pressure. The measured circuit pressure (referenced to the patient wye) at the end of the expiratory phase of a breath. If expiratory pause is active, the displayed value reflects the level of any active lung PEEP.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

$PEEP_I$	Intrinsic PEEP. Indicates a calculated estimate of the pressure above the PEEP level at the end of exhalation. Determined during an expiratory pause maneuver.
P_I	Inspiratory pressure. The operator-set inspiratory pressure at the patient wye (above PEEP) during a pressure control (PC) mandatory breath.
PI	Inspiratory pressure transducer.
$P_{I\ END}$	End inspiratory pressure. The pressure at the end of the inspiration phase of the current breath. If plateau is active, the displayed value reflects the level of end-plateau pressure.
PIM	Patient-initiated mandatory breath. A mandatory breath triggered by patient inspiratory effort.
P_{MEAN}	Mean circuit pressure, a calculation of the measured average patient circuit pressure over an entire respiratory cycle.
P_{PEAK}	Maximum circuit pressure, the maximum pressure during the inspiratory and expiratory phases of a breath.
primary alarm	An initial alarm.
PS	Pressure support, a spontaneous breath type in which the ventilator delivers an operator-set pressure (in addition to PEEP) during the inspiratory phase. Available in SPONT, SIMV, and BiLevel modes.
P_{SENS}	Pressure sensitivity. The operator-set pressure drop below PEEP (derived from the patient's inspiratory flow) required to begin a patient-initiated breath when pressure triggering is selected.
PSOL	Proportional solenoid valve.
P_{SUPP}	Pressure support. A setting of the level of inspiratory assist pressure (above PEEP) at the patient wye during a spontaneous breath (when spontaneous breath type is PS).
P_{-TRIG}	Pressure triggering, a method of recognizing patient inspiratory effort in which the ventilator monitors pressure in the patient circuit. The ventilator triggers a breath when the airway pressure drops by at least the value selected for pressure sensitivity (P_{SENS}).
remedy message	A message displayed on the GUI during an alarm condition suggesting ways to resolve the alarm.
resistance	The flow-dependent pressure drop across a conduit. Measured in $cmH_2O/L/s$ or hPa/L/s.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

restricted phase of exhalation	The time period during the exhalation phase where an inspiration trigger is not allowed. The restricted phase of exhalation is defined as the first 200 ms of exhalation, OR the time it takes for expiratory flow to drop to ≤ 50% of the peak expiratory flow, OR the time it takes for the expiratory flow to drop to ≤ 0.5 L/min (whichever is longest). The restricted phase of exhalation will end after five (5) seconds of exhalation have elapsed regardless of the measured expiratory flow rate.
rise time %	A setting that determines the rise time to achieve the set inspiratory pressure in pressure-controlled (PC), VC+, BiLevel, or pressure-supported (PS) breaths. The larger the value, the more rapid the rise of pressure.
safety net	The ventilator's strategy for responding to patient problems and system faults.
safety valve (SV)	A valve residing in the ventilator's inspiratory module designed to limit pressure in the patient circuit. When open, it allows the patient to breathe room air (if able to do so).
safety ventilation	A mode of ventilation active if the patient circuit is connected before ventilator startup is complete, or when power is restored after a loss of five (5) minutes or more.
service mode	A ventilator mode providing a set of services tailored to the needs of testing and maintenance personnel. When in the service mode, the ventilator does not provide ventilation.
SIMV	Synchronous intermittent mandatory ventilation. A ventilatory mode in which the ventilator delivers one mandatory breath per breath cycle and as many spontaneous breaths as the patient can trigger during the remainder of the breath cycle.
SIS	Sleeved index system. A standard for high pressure gas inlet fittings.
soft bound	A ventilator setting that has reached its recommended high or low limit, accompanied by an audible tone. Setting the ventilator beyond this limit requires the operator to acknowledge a visual prompt to continue.
SPONT	Spontaneous. A ventilatory mode in which the ventilator delivers only spontaneous breaths. In SPONT mode, the patient triggers all breaths delivered by the ventilator with no set mandatory respiratory rate. The patient controls the breath variables, potentially augmented by support pressure.
spontaneous type	A setting that determines whether spontaneous breaths are pressure-supported (PS), tube-compensated (TC), volume-supported (VS), or proportionally assisted (PAV).
SST	Short self test. A test that checks circuit integrity, calculates circuit compliance and filter resistance, and checks ventilator function. Operator should run SST at specified intervals and with any replacement or alteration of the patient circuit.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

STPD	Standard temperature and pressure, dry. Defined as dry gas at a standard atmosphere (760 mmHg, 101.333 kPa, approximately 1.0 bar) and 0°C.
SVO	Safety valve open. An emergency state in which the ventilator opens the safety valve so the patient can breathe room air unassisted by the ventilator (if able to do so). An SVO state does not necessarily indicate a ventilator inoperative condition. The ventilator enters an SVO state if a hardware or software failure occurs that could compromise safe ventilation, with the loss of the air and oxygen supplies, or if the system detects an occlusion.
system fault	A definition used by the ventilator's safety net. System faults include hardware faults (those that originate inside the ventilator and affect its performance), soft faults (faults momentarily introduced into the ventilator that interfere with normal operation), inadequate supply (AC power or external gas pressure), and patient circuit integrity (blocked or disconnected circuit).
T_A	Apnea interval, the operator-set variable that defines the breath-to-breath interval which, if exceeded, causes the ventilator to declare apnea and enter apnea ventilation.
Tb	Breath time cycle during mechanical ventilation.
T_E	Expiratory time. The expiratory interval of a breath. Also the operator-set timing variable that determines the expiratory period for pressure-controlled (PC) or VC+ mandatory breaths.
technical alarm	An alarm occurring due to a violation of any of the ventilator's self monitoring conditions, or detected by background checks.
T_I	Inspiratory time, the inspiratory interval of a breath. Also, the operator-set timing variable that determines the inspiratory interval for pressure-controlled (PC) or VC+ mandatory breaths.
Tm	Mandatory interval portion of SIMV breath cycle; it is reserved for a PIM.
T_{PL}	Plateau time. The amount of time the inspiration phase of a mandatory breath is extended after inspiratory flow has ceased and exhalation is blocked. Increases the residence time of gas in the patient's lungs.
Ts	Spontaneous interval portion of SIMV breath cycle; it is reserved for spontaneous breathing throughout the remainder of the breath cycle.
$\dot{V}_{E\ TOT}$	Minute volume, the expiratory tidal volume normalized to unit time (L/min). The displayed value is compliance- and BTPS-compensated.
VBS	Ventilator breathing system. Includes the gas delivery components of the ventilator the patient circuit with tubing, filters, humidifier, and other accessories; and the ventilator's expiratory metering and measurement components.

Table Glossary-1. Glossary of Ventilation Terms (Continued)

VC	Volume control, a mandatory breath type in which the ventilator delivers an operator-set tidal volume, peak flow, and flow pattern. Available in A/C and SIMV modes, and for operator-initiated mandatory (OIM) breaths in SPONT mode.
Ventilation Assurance	A feature on the 980 Series Ventilator which enables ventilation to continue when a critical system error occurs, by entering the Backup Ventilation (BUV) state.
Ventilator Inoperative (vent inop)	An emergency state the ventilator enters if it detects a hardware failure or a critical software error which could compromise safe ventilation. During a ventilator inoperative condition, the safety valve opens to allow the patient to breathe room air (if able to do so) unassisted by the ventilator. Qualified service personnel must power up the ventilator and run EST before normal ventilation can resume.
VIM	Ventilator-initiated mandatory breath. A breath that is delivered at a time determined by the ventilator
$\dot{V}_{MAX}$	Peak flow. A setting of the peak (maximum) flow of gas delivered during a VC mandatory breath. (Combined with tidal volume, flow pattern, and plateau, constant peak flow defines the inspiratory time.) To correct for compliance volume, the ventilator automatically increases the peak flow.
$\dot{V}_{SENS}$	Flow sensitivity. A setting that determines the rate of flow inspired by the patient that triggers the ventilator to deliver a mandatory or spontaneous breath (when flow triggering is selected).
V_T	Tidal volume. A setting that determines the volume inspired and expired with each breath. The V_T delivered by some Puritan Bennett ventilators is an operator-set variable that determines the volume delivered to the patient during a mandatory, volume-based breath. V_T is compliance-compensated and corrected to body temperature and pressure, saturated (BTPS).
$\dot{V}_{-TRIG}$	Flow triggering. A method of recognizing patient inspiratory effort in which the ventilator monitors the difference between inspiratory and expiratory flow measurements. The ventilator triggers a breath when the difference between inspiratory and expiratory flows increases to a value that is at least the value selected for flow sensitivity ($\dot{V}_{SENS}$.

Table Glossary-2. Units of Measure

cm	Centimeter. A unit of length.
ft	Feet. A unit of length.
Hz	Hertz. A unit of frequency, indicating cycles per second.
kg	Kilogram. A unit of weight

Table Glossary-2. Units of Measure (Continued)

L	Liter. A unit of volume
lb	Pound. A unit of weight.
m	Meter. A unit of length.
mL	Milliliter. A unit of volume.
ms	Millisecond. A unit of time.
s	Second. A unit of time
V	Volts. A unit of voltage
VA	Volt-amperes. A unit of power.

Table Glossary-3. Technical Abbreviations

AC, also ac	Alternating current. The movement of electrical charge that periodically reverses direction.
ASCII	American Standard Code for Information Interchange. A standard character encoding scheme.
CE	A certification mark issued under the authority of the European Common Market that indicates compliance with the Medical Device Directive, 93/42/EEC.
CSA	Canadian Standards Association.
CRC	Cyclic Redundancy Check or Code. An algorithm or a computational result based on the remainder of a division defined over the ring of polynomials in the Galois field GF(2). CRC algorithms are the basis for data integrity checks.
DC, also dc	Direct current. The movement of electrical charge flowing in a single direction.
EMC	Electromagnetic compatibility.
EN	European norm (referring to the European Common Market).
ETO	Ethylene oxide.
IEC	International Electrotechnical Commission. A standards organization.
ISO	International Standards Organization. A standards organization.
LCD	Liquid crystal display. A type of visual equipment-operator Interface.
LED	Light-emitting diode. A means of providing visual indications.
MRI	Magnetic resonance imaging.

Table Glossary-3. Technical Abbreviations (Continued)

NVRAM, also NovRam	Non-volatile random access memory. Memory that is kept active across resets and power cycles and is not normally initialized at startup.
POST	Power-on self-test. Software algorithms to verify the integrity of application software and the hardware environment. Power-on self-test generally occurs at power on, after power loss, or when the device resets due to a detected fault.
RAM	Random access memory.

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